



## Complications of ventilation tube insertion in otitis media with effusion

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<b>ARTICLE HISTORY</b>	<b>Abstract:</b> Otitis media with effusion (OME) is the accumulation of fluid in the middle ear space without any symptoms of inflammation. It leads to decreased hearing and delayed speech in children. It is treated by ventilation tube insertion. These tubes may have complications itself like otorrhea, eardrum atrophy, perforation, serous otitis media, and tympanosclerosis. The aim of this study is to evaluate the complications of ventilation tube insertion in 100 cases done at specialty surgical center of otolaryngology/Benghazi over a period of one year (January 2021 to December 2021). Complications was seen in 42% of the cases, the most frequent complication was otorrhea followed by tympanosclerosis. the least encountered complication was tympanic membrane atrophy. Serious complications may be seen in some cases like cholesteatoma but it was not reported in this series. There was no statistically difference between male and female in terms of post-operative complications. It is advised to follow up these operated cases regularly to diagnose any complication and treat it early and properly.
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### مضاعفات زراعة انابيب التهوية في حالات ارتشاح الاذن الوسطي

<b>الكلمات المفتاحية:</b> ارتشاح الاذن الوسطي، زراعة انابيب التهوية، مضاعفات.	<b>المستخلص:</b> ارتشاح الاذن الوسطي هو تجمع سائل في تجويف الاذن الوسطي دون وجود علامات التهاب به. يصيب الكبار والصغار ولكنه أكثر شيوعا عند الأطفال ويؤدي الي نقص في السمع وبالتالي تأخر النطق عند الاطفال. تحتاج هذه الحالات الي تصريف السائل جراحيا وزراعة انابيب تهوية في الاذن الوسطي لمنع تجمع ه مرة اخري، هذا الاجراء لا يخلو من مضاعفات مثل افرازات الاذن المزمن، تصلب غشاء الطبلية، ترقق غشاء الطبلية وربما ثقبها أيضا. الغرض من الدراسة هو تقييم هذه المضاعفات وأثرها على المريض مستقبلا. أجريت الدراسة على 100 حالة في فترة سنة في مركز الجراحات التخصصية لراحة الانف والاذن والحنجرة بينغازي. كانت نسبة المضاعفات 42% أشهرها افرازات الاذن المتكررة عند 14% من الحالات واقلها ترقق الطبلية 5%. من المضاعفات النادرة الحدوث هي تسوس اللثة ويحدث بنسبة ضئيلة جدا، لم نسجل أي إصابة من هذه المضاعفات في دراستنا، كما لم يكن هناك فرق بين الذكور والاناث من حيث حدوث مضاعفات عندهم من عدمها. ننصح بمتابعة مثل هذه الحالات بصفة دورية للتعرف على المضاعفات مبكرا ومعالجها
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## INTRODUCTION

OME is characterized by the accumulation of fluid in the middle ear space without acute inflammation symptoms. It is indeed a common condition in children, especially between the ages of two and five years. In fact, it is estimated that approximately 80% of children experience at least one episode of OME before the age of ten, as supported by the study by (Khanna et al., 2008).

When OME is left untreated, it can lead to various complications, including: (1) Hearing loss due to decreased sound wave transmission in the liquid media of the middle ear that characterize otitis media with effusion. (2) Perforated tympanic membrane by the increased accumulation of fluid in the middle ear space. (3) Prolonged fluid accumulation and negative pressure in the middle ear causes thinning and retraction of the ear drum which predisposes to adhesive

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otitis media.(4)Tympanosclerosis: due to formation of calcium deposits or scarring on the eardrum or middle ear bones, which can affect hearing. (5)Sever retraction and adhesive otitis media may predispose to cholesteatoma in rare occasions.

Early diagnosis and appropriate management of OME are important to prevent or minimize the risk of these complications. Prolonged deprivation of hearing can result in language, speech, and cognitive development disorders, as well as academic difficulties especially in children (da Costa Monsanto et al., 2016). mechanical obstruction of Eustachian tube by enlarged adenoids or oedema secondary to allergy or infection can also cause eustachian tube dysfunction and contribute to otitis media with effusion (Kamrani K et al., 2008; Shaffer et al., 2018)

One of the most effective treatments for OME is to aerate the middle ear through the insertion of ventilation tubes (Yang et al., 2012). There are two main types of ear tubes: short-term and long-term tubes (Heidemann, 2015). each type of these tubes have complications and benifets. Reports have indicated several complications associated with ventilation tube insertion, such as otorrhea, tympanosclerosis, persistent perforation, eardrum stretching, cholesteatoma, and ventilation tube granuloma (Branco et al., 2017; Nogan et al., 2017). In many cases, it can be challenging to distinguish between complications resulting from the disease itself and those resulting from the treatment. Otorrhea, is the most common complication of ventilation tube insertion and can occur in 3% to 50% of cases (van Dongen et al., 2015).

**Aims of the study:** The aim of this study is to determine the complications associated with ventilation tube (VT) insertion surgery conducted at the specialized surgical center (SSC) for Otolaryngology in Benghazi, Libya.

## MATERIALS AND METHODS

**Study design:** This study is cohort study design of one hundred patients who have been surgically treated by ventilation tube insertion at SSC. Demographic questionnaire, which gathers information on age, sex, reasons for surgery, and date of surgery has been applied to collect the data. Additionally, patient medical records will be examined to gather data on complications and symptoms. Follow-up will be conducted over a period of 2 months to 1 year to assess any complications.

**Study settings:** Data collection from January 2021 to December 2021. The final sample size will be compared to existing literature, and the incidence of postoperative complications related to myringotomy and ventilation tubes will be approximately calculated.

### **Inclusion criteria:**

OME that required myringotomy and ventilation tube insertion,nsertion of bilateral or unilateral ventilation tubes and placement of the grommet or T-tube style of tube,

### **The exclusion criteria:**

Craniofacial anomalies such as cleft lip or palate, patients requiring repeat ventilation tube insertion and in cases where concurrent diseases that affect the eardrum are present or there are incomplete medical records, additional considerations will be taken into account.

In order to obtain informed consent, the study population and parents will be provided with comprehensive information about the purpose and procedure of the study. They will be informed about the potential risks and benefits of participating in the study. Clear explanations will be given regarding the collection and use of their medical data for research purposes. Participants will be invited for re-examination and interviews to gather more detailed information about their medical history, concurrent dis-

eases, and any relevant factors that may impact the study outcomes. These interviews will help in ensuring that accurate and comprehensive data is obtained for analysis. Privacy and confidentiality of the participants' information will be maintained throughout the study process.

Risk factors for OME (Otitis Media with Effusion) include passive smoking, bottle feeding, day-care nursery attendance, and atopy. Both children and adults can develop OME, but the underlying causes may differ between these age groups. In children, OME is more common due to anatomical factors. The Eustachian tube, is positioned more horizontally in younger children. As children grow up and develop into adults, the Eustachian tube elongates and angles caudally, reducing the risk of OME. Therefore, the prevalence of OME is higher in children compared to adults (Nemade et al., 2018).

Developmental anomalies related to the palate, palate muscles, decreased muscle tone in the palate muscles, and variations in bone development can increase the risk of OME in children. Conditions such as cleft palate and Down syndrome, which affect the structure and function of the Eustachian tube and mucociliary clearance, are associated with a higher susceptibility to OME. These factors has an effect on the accumulation of fluid in the middle ear.

OME seen more common between the ages of one and six years. The highest age group affected is at two years. The incidence of OME tends to decrease after the age of five. young children are particularly vulnerable to OME, likely due to factors such as the immaturity of the Eustachian tube and increased susceptibility to upper respiratory infections.

OME is more prevalent during the winter months, which corresponds to a higher incidence of upper respiratory infections. Upper respiratory infections can lead to inflamma-

tion and congestion of the Eustachian tube, impairing its normal function and contributing to the development of OME. Early detection, treatment, and regular follow-up are essential in children at increased risk of OME to prevent complications and mitigate the impact on hearing and development. Children with OME may exhibit signs of inattention or decreased academic performance Esposito S et al. The presence of fluid in the middle ear can affect hearing, leading to difficulties in understanding speech and potentially affecting a child's ability to focus and learn.

Large adenoids, may cause obstruction of the Eustachian tube can lead to poor ventilation of the middle ear, which leads to the development of OME. The adenoids can also serve as a reservoir of bacteria that enter the Eustachian tube, leading to the growth of biofilms and inflammation. This inflammation can further contribute to blockage and the accumulation of fluid in the middle ear. (Searight et al., 2023). The mucociliary defense system in the Eustachian tube is the first line of defense in the middle ear. Immunoglobulins which are produced by the mucosa play a role in this defense system. In OME, there is a significant elevation of these immunoglobulins in the effusions, suggesting that the defense system may stimulated (Schilder et al., 2016) treatment of allergic rhinitis, which is often associated with OME, may be beneficial for patients. Allergies can contribute to the development of OME, and addressing allergic symptoms may help alleviate OME in these cases.

Hearing loss is a common complaint in patients with OME. Patients or parents may notice communication difficulties, withdrawal, and lack of attention. During examination, clinicians may observe impaired speech and language development. Patients may also experience intermittent otalgia (ear pain), aural fullness (sensation of pressure or blockage in the ear), or a sensation

that the ear is popping (Skoner et al., 2009).

Childhood hearing loss can indeed have an impact on language development, and hearing aids are often considered a non-invasive option for treating OME. However, for cases of persistent OME where long-term changes in the middle ear and tympanic membrane occur, resulting in permanent hearing loss, ventilation tubes may be recommended (Gan et al., 2017; Schilder et al., 2016). The insertion of ventilation tubes aims to improve the ventilation of the middle ear, equalizing its pressure with the atmosphere, which can lead to improved hearing (Esposito et al., 2021).

There are two main types of ventilation tubes: short-term and long-term. Short-term tubes are smaller and typically remain in place for six months to a year before eventually coming out on their own. On the other hand, long-term tubes tend to stay in place for a longer duration, ranging from 20.6 to 35 months. However, it is worth noting that around 20% of ears that undergo ventilation tube insertion may require additional procedures within two years of the initial insertion (Ferlito et al., 2020).

(Ferlito et al., 2020; Vlastarakos et al., 2007) had studied the potential morbidity and complications associated with ventilation tube insertion (VTI). According to them, VTI, despite being a routine procedure, can be associated with significant morbidity. Complications related to VTI were reported to occur in 17% to 80% of operated ears, depending on specific circumstances of children. It is important to note that the complications and their frequencies can vary from patient to another due to different factors such as the patient population, surgical technique, follow-up protocol, and other individual characteristics. While VTI is generally considered a safe and effective intervention for certain cases of otitis media with effusion (OME), the potential complications should be taken into

account. Some of the reported complications associated with VTI may include otorrhea, tube obstruction or extrusion, persistent perforation of the tympanic membrane, tympanosclerosis, and granulation tissue formation.

Appropriate postoperative care and follow-up are mandatory to monitor and manage any complications that may arise. It can be challenging to differentiate between the sequelae resulting from the disease itself and those arising from the treatment. VTs are advised for the treatment of OME to reduce complications of the condition. OME can have significant consequences, including hearing loss, which can impact speech and language development in children. By inserting VTs, normalization of pressure in the middle ear and drainage of fluid can help reduce these adverse effects and improve hearing.

Furthermore, severe complications, such as cholesteatoma, can potentially arise from untreated or recurrent OME but this is very rare complication of the disease and the insertion of the tube itself by implanting squamous epithelium in the middle ear. Regarding the complications associated with VT insertion, otorrhea is the most common complication reported in children. Otorrhea can occur due to infection or inflammation around the ventilation tube, and it typically resolves with appropriate treatment. Regular follow-up and proper care of the VT site, keeping the ear dry, can help minimize the risk and manage otorrhea effectively. The incidence of early otorrhea varies from 7% to 34%, while delayed otorrhea occurs in 12-24% of cases. Recent studies have reported a higher percentage, reaching 47.3%. However, in Ferlito's series, the incidence of early and late otorrhea is lower (3.4% and 8.6%) compared to the literature.

According to the study by (Esposito et al., 2021), several factors have been noticed as

potential risk factors of postoperative otorrhea. These factors include:

1. Younger children may have a higher risk of postoperative as differences in immune response, anatomy, and susceptibility to infections are more in younger children.
2. Mucoïd effusion can provide a favorable environment for bacterial growth and increase the risk of infection.
3. Adequate antibiotic treatment can help prevent or manage infections and reduce the incidence of otorrhea especially in the post-operative period..
4. Contamination of the external auditory canal during or after the surgery may introduce bacteria that can cause otorrhea. Sterile techniques and proper postoperative care can help minimize this risk.
5. Bleeding at the operation site may contribute to the development of otorrhea. As blood in the middle ear can serve as a medium for bacterial growth and increase the risk of infection.
6. Concurrent upper respiratory tract infections, such as the common cold, can increase the likelihood of postoperative otorrhea as it spreads to the middle ear.

However, the study by (Esposito et al., 2021). suggests that gastric reflux does not appear to play a significant role in the pathogenesis of post-tympanostomy otorrhea. Gastric reflux occurs when stomach acid flows back into the esophagus, and it was not found to be a major contributing factor to postoperative otorrhea following VTI.

The use of local antibiotic or antibiotic-steroid drops after VTI is considered useful by some authors, while others consider it ineffective or contraindicated. The low incidence of otorrhea could be attributed to strict water precautions following VTI (Skoner et al., 2009).

Adenoïdectomy performed in conjunction with VTI may be a factor contributing to a

reduction in the rate of otorrhea. Some authors have reported that VTI with adenoïdectomy was associated with a lower number of otorrhea episodes (Ferlito et al., 2020). Adenoïdectomy has been found to reduce the need for additional VTI, and previous data suggest that post-operative otorrhea significantly increases both the rate of tube extrusion and the need for subsequent VTI (Monasta et al., 2012).

Medial migration of VTs refers to the movement of the tube from its original position towards the middle ear cavity has been rarely reported in the literature from 0% to 1.1%, indicating its infrequent nature.

Medial migration of VTs is considered the fifth most common indication for tympanostomy tube removal as it is no longer serve its intended purpose of ventilation and to prevent middle ear complications. This complication can be due to technical errors during the insertion or may occur later due to factors such as persistent negative middle ear pressure. The migration of tubes into the middle ear space can contribute to severe middle ear pathology, and some authors recommend their prompt removal (Cunningham et al., 1993; Schilder et al., 2016).

Tympanostomy tube blockage has also been observed, with rates ranging from 11% to 12%. The use of pre-operative eardrops has been reported to significantly reduce the rate of VT blockage from 13.1% to 1.6%. However, obstruction of the VT can also occur due to concretions of ototopical medications. This blockage can influence the probability of early extrusion of the VT (Bassim & Drake, 2005). Regular follow-up can contribute to a low incidence of tympanostomy tube blockage as early identification helps prompt management .

According to the study by (Barati et al., 2012), long-term ventilation tube insertion can lead to eardrum atrophy in the area

where the tube is inserted. Eardrum atrophy refers to the thinning and weakening of the tympanic membrane in that specific region over time, this can result in atrophy, which may manifest as thinning, retraction, or other structural changes in the eardrum. Eardrum atrophy has a potential predisposition to permanent perforation. It is important to monitor the condition of the eardrum during long-term ventilation tube placement and assess for any signs of atrophy or other structural changes. In cases where eardrum atrophy is observed or a permanent perforation occurs, further intervention or surgical treatment may be required to address the issue and restore normal middle ear function..

Granulation tissue is a predisposing factor for otorrhea. In cases where granulation tissue is present, the use of antibiotic-corticosteroid drops has been reported to eliminate the tissue, making tube removal unnecessary. Tympanic retraction is considered a complication after VTI, although it is more commonly associated with the underlying disease itself due to poor tube ventilation. Residual tympanic perforation, on the other hand, is associated with the duration of tube retention and the number of tube insertions. The prevalence of residual tympanic perforation varies, with rates ranging from 2-3% after the use of short-duration tubes and 14-24% after the use of long-duration tubes (Searight et al., 2023).

Myringosclerosis is a progressive and late event, primarily considered an aesthetic rather than functional sequel to VTI. It does not significantly impact hearing. The incidence of myringosclerosis reported in Ferlito's study (36.2%) is consistent with the percentages reported in the literature (23-70%). Myringosclerosis most frequently occurs (82.7%) in the quadrant of the tympanic membrane where the ventilation tube was inserted. Cholesteatoma is the most severe potential complication following VTI, but it occurs in a relatively small percentage

of cases, approximately between 0.1% and 1% (Golz et al., 1999).

Recurrence of OME after ventilation tube extrusion may occur in some cases and it had been mentioned in different studies.

1. (Yaman et al., 2010). reported a recurrence rate of 20.7% in ears after the extrusion of Shepard tubes.
2. (Talmon et al., 2001) using T-tubes, reported a reinsertion rate of 4.9% of cases.
3. (Valtonen et al., 2005) found a higher recurrence rate of repeated ventilation tube insertion (VTI) in 53.2% of ears with OME. This study suggests that over half of the ears with OME required multiple VTIs.

Furthermore, the age of the child and the type of tube used can influence the recurrence rates:

1. (Iwaki et al., 1998) observed that the recurrence rate of OME was higher in the age range of 2 to 5 years compared to 7 to 8 years. This suggests that younger children may have a higher risk of OME recurrence after tube extrusion.
2. The study also found that Shepard tubes had a higher recurrence rate compared to T-tubes. This implies that the choice of tube type may impact the likelihood of OME recurrence.

Regarding patient demographics, (Ferlito et al., 2020) noted that male children were more likely to undergo VTI than female children, which is consistent with previous studies. Their analysis did not find a significant influence of patient age at surgery on sequelae and/or complications rates, although it's worth noting that there were no children younger than three years old included in the study, so this finding may differ in a larger population including younger cases (Ferlito et al., 2020). VT placement in children generally does not result in peri-

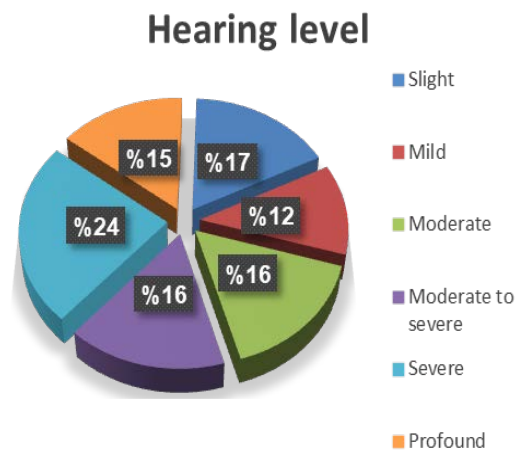
operative or immediate postoperative complications. However, the use of long-term tubes is associated with a higher incidence of complications such as otorrhea and residual perforation compared to short-term tubes. Cunningham MJ et al. reported a lower incidence of early and delayed otorrhea in their study compared to previous studies.

Swimming or bathing can potentially facilitate the entry of bacteria into the middle ear through the ventilation tube, increasing the risk of infection. Factors contributing to the low incidence of complications after VTI are difficult to establish conclusively. However, some potential factors that may contribute to a lower incidence include older patient age at the time of initial tube placement, the use of short-duration tubes, concurrent adenoidectomy, appropriate and regular follow-up by the same investigator, and strict water precautions after tympanotomy (Bassim & Drake, 2005).

Close and careful observation at each follow-up visit, including microscopic cleaning, especially at 2 months and 1 year after tube extrusion, can help minimize silent sequelae and prevent more severe pathologies of the eardrum and middle ear, which could lead to chronic otitis media and hearing problems later in life (Subramaniam et al., 2015). Similarly, determining the ideal type of ventilation tube can vary based on factors such as the patient's age, ear anatomy, and specific clinical indications. Different types of tubes, such as Shepard tubes and T-tubes, have been used with varying success rates and potential complications. Regarding the study by (Vahedian et al., 2020), they observed several surgical complications associated with tube placement, including otorrhea, eardrum atrophy, perforation, serous otitis, and tympanosclerosis. These findings are consistent with similar studies that have reported complications related to ventilation tube insertion.

## RESULTS

A total number of 100 participants participated in this prospective study. The mean age was  $4.9 \pm 1.5$  years among the participants. There were 36% males and 64% females. Among the participants; 5% had family history of the same illness while 95% had not. Upon assessing hearing level, 17% had slight hearing loss, 12% had mild hearing loss, 16% had moderate hearing loss, 16% had moderately severe hearing loss, 24% had severe hearing loss, and 15% had profound hearing loss as in fig.no.1.



**Figure (1).** Hearing level among the included group.

Persistent otorrhea is the most common complication occurring in 14% and second in frequency is tympanosclerosis which is common among 9% of the participants. Persistent perforation is the third most common complication among 8% of the participants. Then serous otitis media occurred among 6% of the included participants while the least common was eardrum atrophy (5%). As seen in table No. 1

**Table (1).** Complications of the VTI among the included participants.

Persistent otorrhea	14	14%
Tympanosclerosis	9	9%
Persistent perforation	8	8%
Serous otitis media	6	6%
Tympanic membrane atrophy	5	5%
Total	42	42%

It is interesting to note. If table No.2 indicated that there was no statistically significant difference between males and females in terms of postoperative complications of VT insertion, including persistent otorrhea, eardrum atrophy, persistent perforation, serous otitis media, and tympanosclerosis, it suggests that the occurrence of these complications was similar in both males and females. In other words, the data did not show a significant association between gender and the risk of these complications following VT insertion.

**Table (2).** Comparison between both gender regarding complications.

Variable		Male n= 36	Female n= 64	P value
Persistent otorrhea	Yes	8 (22.2)	58 (90.6)	0.130
	No	28 (77.8)	6 (9.4)	
Eardrum atrophy	Yes	1 (2.8)	4 (6.3)	0.651
	No	35 (97.2)	60 (93.8)	
Persistent perforation	Yes	2 (5.6)	6 (9.4)	0.707
	No	34 (94.4)	58 (90.6)	
Serous otitis media	Yes	2 (5.6)	4 (6.3)	>0.999
	No	34 (94.4)	60 (93.8)	
Tympanosclerosis	Yes	3 (8.3)	6 (9.4)	>0.999
	No	33 (91.7)	58 (90.6)	

Chi square test; Fisher Exact test; \*p is significant at <0.05

## DISCUSSION

According to (Restuti et al., 2022) untreated OME can lead to various consequences. These include hearing loss, eardrum rupture, adhesive otitis media, tympanosclerosis, and cholesteatoma. Hearing loss is a significant consequence of OME and can have a negative impact on various aspects of a person's life. In children, hearing loss due to OME can cause difficulties in language, speech, and cognitive development. It may lead to delays in acquiring language skills and affect communication abilities, which can subsequently impact academic performance. It's important to note that timely diagnosis and appropriate management of OME can help prevent or mitigate these consequences. Seeking medical attention, obtaining proper treatment, and ad-

ressing any underlying issues can significantly improve outcomes and reduce the potential impact on language, speech, and academic performance.

The key clinical-pathologic cause in otitis media is hypoventilation of the middle ear and serous fluid or mucoid collection. Eustachian tube dysfunction is commonly regarded as a significant element in the pathophysiology of this condition. Microorganisms enter the middle ear as a result of eustachian tube dysfunction, which results in air pressure and fluid buildup in the middle ear and precludes middle ear cleansing (MacKeith et al., 2022). The nasopharynx is the site of infection in 91% of patients, and the adenoid serves as a reservoir for harmful microorganisms. Otitis media and Eustachian dysfunction can both be brought on by enlarged adenoids (Searight et al., 2023).

(MacKeith et al., 2022). demonstrated that one of the greatest OME therapies is the ventilation tube (MacKeith et al., 2022). Furthermore, (Kancherla et al., 2022) cleared that reducing the incidence of future ear infections, treating hearing loss caused by middle ear fluid, improving speech and balance issues, are some advantages of ventilation tube insertion (Kancherla et al., 2022). The insertion of a ventilation tube has been shown to have a number of negative consequences on the tympanic membrane. Otorrhea, tympanosclerosis, chronic perforation, eardrum stretching, cholesteatoma, and ventilation tube granuloma are a few surgical problems associated with the installation of ventilation tubes. In many instances, it is challenging to discern between complications caused by the therapy and complications caused by the disease (Sogebi & Oyewole, 2022).

The most frequent ventilation tube problem, which can happen between 3% and 50% of the time, is otorrhea. Searight revealed that otorrhea affects two out of every three kids with VT every year. There isn't much proof



that taking measures when around water helps stop this sickness.(Searight et al., 2023). One of the key causes of tympanosclerosis, is frequently linked to myringotomy and VT insertion. Tympanosclerosis also has another etiology that involves bleeding into the eardrum (Mulvaney et al., 2022).

The study was aiming to evaluate the complications of VT insertion surgery in The speciality surgical center for Otolaryngology/ Benghazi/ Libya. This prospective study was carried out on 100 patients who underwent VT insertion surgery. The target samples were taken over a period of one year. Final sample size was compared to the found literature and the incidence of post-operative complications of myringotomy and ventilation tubes were approximately calculated. Regarding the demographic data in our study, the mean age was  $4.9 \pm 1.5$  years among the participants. There were 36% males and 64% females. 49% participated and followed up in 2020 and 51% included in 2021. Among the participants, 5% had family history while 95% had no family history of same illness. Upon assessing hearing level;17% had slight hearing loss, 12% had mild hearing loss, 16% had moderate hearing loss, 16% had moderately severe hearing loss, 24% had severe hearing loss, and 15% had profound hearing loss.

Study by (Vahedian et al., 2020) on (VTI) in children. According to their study, out of the 205 children who underwent VT insertion surgery, approximately 57% were boys, and the remaining surgeries were performed on girls. It's interesting to note that no positive family history was recorded for any of the children in the study. The study by (Vahedian et al., 2020) did not find a higher incidence of complications, including hearing loss, in females compared to males. This finding contradicts some previous studies that have reported higher complications in females. The authors suggest that the non-normal distribution of gender variables in

their study population may have contributed to this inconsistency. They specifically mention the study by (Khalili et al., 2007) which might have reported different results. It's important to consider that the relationship between gender and complications of (OME) and VT insertion can be complex and may vary across different populations and studies. Further research is needed to better understand the potential impact of gender on these complications.

Regarding complications of the VT insertion among our included participants, persistent otorrhea is the most common complication, occurring in 14% and second in frequency is tympanosclerosis which is common among 9% of the participants. Persistent perforation is the third most common complication among 8% of the participants. Then serous otitis media occurred among 6% of the included participants while the least common was eardrum atrophy (5%). There was no statistically significant difference between males and females regarding previously mentioned postoperative complications of VT insertion. studies by (Barati et al., 2012; van Dongen et al., 2015) that support the findings of many surgical complications associated with ventilation tube insertion (VTI) in children.

According to these studies, complications such as otorrhea, eardrum atrophy, perforation, serous otitis, and tympanosclerosis were observed. These complications highlight the importance of closely monitoring children who have undergone VTI to prevent and manage such complications effectively. The findings from these studies emphasize the need for proper care and follow-up after VTI to minimize the risk of complications. Regular monitoring and appropriate management can help detect and address any issues that arise, ensuring optimal outcomes for the children. It's worth noting that each study may have its own specific population and methodology, so the exact incidence and severity of complications may

vary. Nonetheless, the general consensus from multiple studies, including the ones mentioned, underscores the importance of postoperative care and vigilance to prevent and manage surgical complications associated with VTI in children. In the same line with us, (Barati et al., 2012; Klopp-Dutote et al., 2018) demonstrated that there was no statistically significant difference between males and females regarding postoperative complications of VT insertion (Barati et al., 2012; Klopp-Dutote et al., 2018).

These findings came to be inconsistent with the studies by (Hassmann-Poznańska et al., 2010; Yaman et al., 2010) who found a statistically significant difference between males and females regarding postoperative complications of VT insertion (Hassmann-Poznańska et al., 2010; Yaman et al., 2010). In addition, study by (Zielnik-Jurkiewicz et al., 2006) regarding eardrum atrophy after ventilation tube (VT) insertion surgery. According to Zielnik's findings, the incidence rate of eardrum atrophy was the same in both studied groups, indicating no difference in the occurrence of eardrum atrophy after VT insertion surgery. Furthermore, the study did not find a statistically significant difference between males and females concerning the postoperative complications of VT insertion that were previously mentioned. This suggests that gender may not play a significant role in the incidence of these complications.

Analysis conducted by (Vahedian et al., 2020) regarding the relationship between gender, elapsed time after surgery, and insertion of ventilation tubes (VT). According to their analysis, there was no significant relationship between the two groups of boys and girls in terms of elapsed time after the surgery and insertion of VT in different years. In other words, there was no significant difference in the timing of surgery and VT insertion between boys and girls. However, when studying the relationship between age and time of surgery, a significant

difference was observed. The mean age of girls was significantly higher, indicating that girls tended to undergo surgery and VT insertion at a later age compared to boys. The authors suggest that the discrepancy in findings between the relationship of gender with elapsed time after surgery and age at surgery could be attributed to different study locations and different disease distribution. The distribution and prevalence of ear conditions requiring VT insertion may vary between different populations or regions, leading to differences in the timing of surgery and VT insertion among boys and girls.

In the same direction with our findings, Hassmann detected embedded ventilation tube in addition to cases of infections and recurrences with T-tube insertion among the participants of his study (Hassmann-Poznańska et al., 2010).

According to (Kancherla et al., 2022) there is a perspective that suggests a longer duration of time elapsed after surgery may increase the likelihood of developing serious otitis. In other words, the timing of post-surgical follow-up and ongoing monitoring is crucial in identifying and addressing potential complications, particularly serious otitis. This perspective highlights the importance of timely and regular postoperative care and follow-up visits to detect any complications that may arise and take appropriate measures to manage them effectively.

The study by (Vahedian et al., 2020) had several limitations, including:

1. Incomplete records: The presence of incomplete records may have resulted in missing data or reduced sample size, which could potentially affect the reliability and generalizability of the findings.
2. Refusal to cooperate: Patients or parents refusing to cooperate with the study may have introduced selection bias and lim-

ited the representativeness of the sample.

3. Coexisting infections and middle ear diseases: The presence of coexisting infections or other middle ear diseases among the study participants could have influenced the outcomes and introduced confounding factors that were not accounted for.

## CONCLUSION

It is concluded that otitis media with effusion (OME) can lead to long-term changes in the middle ear and tympanic membrane, potentially resulting in hearing loss. Ventilation tubes are commonly used to prevent or mitigate complications associated with OME. However, certain complications can still arise, including persistent otorrhea, tympanosclerosis, serous otitis media, and eardrum atrophy.

To minimize the risk of postoperative complications related to ventilation tube insertion, close monitoring and follow-up are recommended. Regular check-ups and evaluations can help in the early detection and timely treatment of any complications that may arise. This allows for prompt intervention and can potentially prevent the development of more severe issues.

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## REFERENCES

Barati, B., Hashemi, S. M., & Tabrizi, A. G. (2012). Otological findings ten years after myringotomy with tympanostomy tube insertion. *Iranian*

*journal of otorhinolaryngology*, 24(69), 181.

Bassim, M. K., & Drake, A. F. (2005). Tympanostomy tube obstruction related to ototopical drug therapy. *Ear, nose & throat journal*, 84(7), 416-417.

Branco, C., Monteiro, D., & Paço, J. (2017). Predictive factors for the appearance of myringosclerosis after myringotomy with ventilation tube placement: randomized study. *European Archives of Oto-Rhino-Laryngology*, 274, 79-84.

Cunningham, M. J., Eavey, R. D., Krouse, J. H., & Kiskaddon, R. M. (1993). Tympanostomy tubes: experience with removal. *The Laryngoscope*, 103(6), 659-662.

da Costa Monsanto, R., Erdil, M., Pauna, H. F., Kwon, G., Schachern, P. A., Tsuprun, V., Paparella, M. M., & Cureoglu, S. (2016). Pathologic changes of the peripheral vestibular system secondary to chronic otitis media. *Otolaryngology--Head and Neck Surgery*, 155(3), 494-500.

Esposito, S., Bianchini, S., Argentiero, A., Gobbi, R., Vicini, C., & Principi, N. (2021). New approaches and technologies to improve accuracy of acute otitis media diagnosis. *Diagnostics*, 11(12), 2392.

Ferlito, S., Cocuzza, S., Grillo, C., La Mantia, I., Gulino, A., Galletti, B., Coco, S., Renna, C., Cipolla, F., & Di Luca, M. (2020). Complications and sequelae following tympanostomy tube placement in children with effusion otitis media: Single center experience and review of literature. *Acta Medica Mediterranea*, 36(3), 1905-1912.

- Gan, R. W. C., Overton, P., Benton, C., & Daniel, M. (2017). Hearing aids for otitis media with effusion: Do children use them? *International Journal of Pediatric Otorhinolaryngology*, 99, 117-119.
- Golz, A., Netzer, A., Joachims, H. Z., Westerman, S. T., & Gilbert, L. M. (1999). Ventilation tubes and persisting tympanic membrane perforations. *Otolaryngology–Head and Neck Surgery*, 120(4), 524-527.
- Hassmann-Poznańska, E., Goździewski, A., Piszcz, M., & Skotnicka, B. (2010). Long term sequelae of otitis media with effusion during childhood. *Otolaryngologia Polska= The Polish Otolaryngology*, 64(4), 234-239.
- Heidemann, C. H. (2015). Child and Caregiver Quality of Life in Relation to Ventilating Tube Treatment. *SemanticScholar*.
- Iwaki, E., Saito, T., Tsuda, G., Sugimoto, C., Kimura, Y., Takahashi, N., Fujita, K., Sunaga, H., & Saito, H. (1998). Timing for removal of tympanic ventilation tube in children. *Auris Nasus Larynx*, 25(4), 361-368.
- Kamrani K, Nasiri Kalmarzi K, Naseri N, & K., S. (2008). Effects of surfactant on mortality and complications of respiratory distress syndrome in neonates. *Iranian Journal of Pediatric Diseases*, 18(1), 65-70.
- Kancherla, S., Kakollu, L. S., Thomas, J., Bhatnagar, A., Shah, S., & Korah, A. (2022). A clinical study and management of otitis media with effusion in children. *International Journal of Medical Reviews and Case Reports*, 6(11), 16-16.
- Khalili, G., Sajedi, P., Heidari, S. M., & Najmi, S. (2007). Risk factors of re-intubation of patients in intensive care units. *Journal of Isfahan Medical School*, 25(85), 94-87.
- Khanna, R., Lakhanpaul, M., Bull, P., & Group, G. D. (2008). Surgical management of otitis media with effusion in children: summary of NICE guidance. *Clinical Otolaryngology*, 33(6), 600-605.
- Klopp-Dutote, N., Kolski, C., Strunski, V., & Page, C. (2018). Tympanostomy tubes for serous otitis media and risk of recurrences. *International Journal of Pediatric Otorhinolaryngology*, 106, 105-109.
- MacKeith, S., Mulvaney, C. A., Galbraith, K., Marom, T., Daniel, M., Venekamp, R. P., Rovers, M. M., & Schilder, A. G. (2022). Ventilation tubes (grommets) for otitis media with effusion (OME) in children. *The Cochrane Database of Systematic Reviews*, 2022(3).
- Monasta, L., Ronfani, L., Marchetti, F., Montico, M., Vecchi Brumatti, L., Bavcar, A., Grasso, D., Barbiero, C., & Tamburlini, G. (2012). Burden of disease caused by otitis media: systematic review and global estimates. *PloS one*, 7(4), e36226.
- Mulvaney, C. A., Galbraith, K., MacKeith, S., Marom, T., Daniel, M., Venekamp, R. P., & Schilder, A. G. (2022). Antibiotics for otitis media with effusion (OME) in children. *The Cochrane Database of Systematic Reviews*, 2022(4).
- Nemade, S. V., Shinde, K. J., Rangankar, V. P., & Bhole, P. (2018). Evaluation and significance of Eustachian tube angles and pretympnic diameter in HRCT

- temporal bone of patients with chronic otitis media. *World Journal of Otorhinolaryngology - Head and Neck Surgery*, 4(4), 240-245.
- Nogan, S., Phillips, K., & Grischkan, J. (2017). The treatment of otorrhea in children with cleft palate: an institutional review. *Ear, nose & throat journal*, 96(4/5), 164.
- Restuti, R. D., Tamin, S., Nugroho, D. A., Hutauruk, S. M., & Mansyur, M. (2022). Factors affecting the occurrence of otitis media with effusion in preschool and elementary school children: a comparative cross-sectional study. *BMJ open*, 12(9), e065291.
- Schilder, A. G., Chonmaitree, T., Cripps, A. W., Rosenfeld, R. M., Casselbrant, M. L., Haggard, M. P., & Venekamp, R. P. (2016). Otitis media. *Nature reviews Disease primers*, 2(1), 1-18.
- Searight, F. T., Singh, R., & Peterson, D. C. (2023). Otitis Media With Effusion *Stat Pearls [Internet]*: Stat Pearls Publishing.
- Shaffer, A. D., Ford, M. D., Choi, S. S., & Jabbour, N. (2018). Should children with cleft palate receive early long-term tympanostomy tubes: one institution's experience. *The Cleft Palate-Craniofacial Journal*, 55(3), 389-395.
- Skoner, A. R., Skoner, K. R., & Skoner, D. P. (2009). Allergic rhinitis, histamine, and otitis media. *Allergy & Asthma Proceedings*,
- Sogebi, O. A., & Oyewole, E. A. (2022). Prevalence and co-morbidities of adult-onset otitis media with effusion. *Journal of the West African College of Surgeons*, 12(1), 76.
- Subramaniam, V., Manuprasad, S., Kallikkadan, H. H., & Kumar, V. (2015). Otolological and audiological manifestations in cleft lip and cleft palate children: A clinical study. *Int J Otorhinolaryngol Head Neck Surg*, 1(1), 7.
- Talmon, Y., Gadban, H., Samet, A., Gilbey, P., & Letichevsky, V. (2001). Medium-term middle ear ventilation with self-manufactured polyethylene T-tubes for the treatment of children with middle ear effusion. *The Journal of Laryngology & Otology*, 115(9), 699-703.
- Vahedian, M., Salimi, A., Garkaz, O., Abdi, S. T., Donyadideh, S., & Alizadeh, N. (2020). A Study of Surgical Complications of Ventilation Tube Insertion in Children in Central Iran. *Journal of Comprehensive Pediatrics*, 11(3).
- Valtonen, H., Tuomilehto, H., Qvarnberg, Y., & Nuutinen, J. (2005). A 14-year prospective follow-up study of children treated early in life with tympanostomy tubes: Part 1: Clinical outcomes. *Archives of Otolaryngology-Head & Neck Surgery*, 131(4), 293-298.
- van Dongen, T. M., Schilder, A. G., Venekamp, R. P., Ardine de Wit, G., & Van Der Heijden, G. J. (2015). Cost-effectiveness of treatment of acute otorrhea in children with tympanostomy tubes. *Pediatrics*, 135(5), e1182-e1189.
- Vlastarakos, P. V., Nikolopoulos, T. P., Korres, S., Tavoulari, E., Tzagaroulakis, A., & Ferekidis, E.

(2007). Grommets in otitis media with effusion: the most frequent operation in children. But is it associated with significant complications? *European journal of pediatrics*, 166, 385-391.

Yaman, H., Yilmaz, S., Guclu, E., Subasi, B., Alkan, N., & Ozturk, O. (2010). Otitis media with effusion: recurrence after tympanostomy tube extrusion. *International Journal of Pediatric Otorhinolaryngology*, 74(3), 271-274.

Yang, F. F., McPherson, B., & Shu, H. (2012). Evaluation of an auditory assessment protocol for Chinese infants with nonsyndromic cleft lip and/or palate. *The Cleft Palate-Craniofacial Journal*, 49(5), 566-573.

Zielnik-Jurkiewicz, B., Olszewska-Sosińska, O., & Rakowska, M. (2006). Results of treatment with tympanostomy tubes in children with otitis media with effusion. *Otolaryngologia Polska= The Polish Otolaryngology*, 60(2), 181-185.