Surgical management of otitis media with effusion: comparative study between two different materials of ventilation tubes

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Abstract: The aim of this study was to evaluate the effects of two different materials of ventilation tubes on the outcome of the myringotomy as a surgical treatment in otitis media with effusion. This study is a comparative prospective study carried out in ORL-HNS Department in Tanta University Hospital. Population was forty consecutive cases have been proved clinically and audiologically to have bilateral chronic secretory otitis media type (B) tympanometery. Results revealed there is no significant difference in the outcome on using ventilation tubes of two different materials even they have the same shape and caliber. It was found that there is high significant improvement in all symptoms post-operatively by using both types of ventilation tube. Also it was reported that is no significant difference in the degree of improvement in both groups. Also, it was found that there is no significant difference between silicon tube and Fluroplastic tube regarding the Post-operative complications. Our study showed that there is no significant difference in the outcome on using ventilation tubes of two different materials even they have the same shape and caliber.

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1. Introduction

Otitis media with effusion (OME) is a common cause of hearing difficulties and one of the most frequent reasons for elective admission to hospital for surgery in children.[1]The main factors predisposing to development of otitis media with effusion (OME).

Is a combination of Eustachian tube dysfunction and infection.[2]

Adenoid hypertrophy can contribute to the incidence of OME through causing obstruction of ET. In addition, OME may be secondary to chronic nasopharyngeal infection in the adenoidal tissue. Another mechanism is the allergic reaction that occurs in the mucosal membrane of the nasopharynx and/or its related structures such as lymphatic or adenoid tissue. The released mediators affect secondarily, through the nasopharyngeal secretions, the peritubal and tubal mucosa of ET and then that of the middle ear cavity.[4, 5]

Surgical management of otitis media with effusion should be limited to chronic persistent conditions which is classically treated with myringotomy and placement of ventilation tube.[6] Ventilation tubes have been used as a common treatment for (OME) when medical treatment failed for 6 to 12 weeks. Their role is to replace the function of the Eustachian tube and to prevent serious squeal of otitis media with effusion.[7]However; the use of ventilation tubes is not without serious consequences as post-operative otorrhoea. Other complications include; progressive myringosclerosis, local atrophy, retracted pocket and persistent perforation.[8]

The aim of this study is to evaluate the effect of using of ventilation tubes of two different materials (one of them is Fluoroplastic Material another one is Silicone Material) on the outcome of myringotomy operation.

2. Patients and Methods

This study included 40 patients have been proved clinically and audiologically to have bilateral chronic secretory otitis media type (B) tympanometry.

Ventilation tubes of two different materials were used in this study having the same shape and caliber:

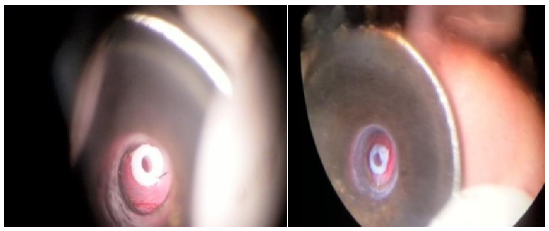

Figure (1): **Fluoroplastic**tube the right ear. Figure (2): **Silicone** tube in the left ear.

1-Fluoroplastic Material Ventilation tube was inserted in the right ear for all patients (fig1).

2-Silicone Material Ventilation tube was inserted in the left ear for all patients (fig2).

These patients were subjected to:

1. Detailed history taking.
2. Complete general examination.
3. Complete ENT examination.
4. Otoscopic and microscopic examination of ears, Audiological evaluation, pure tone audiometry and Tympanometry.
5. Routine investigations for anesthesia.

Exclusion criteria:

1. Patient with unilateral middle ear effusion.
2. Patients with middle ear effusion when the history was less than three months.
3. Cases who didn't receive adequate and appropriate medical treatment for adequate duration.
4. Patients with history of previous myringotomy with or without ventilation tube.
5. Patients with nasopharyngeal masses.
6. Patients with history of radiotherapy.
7. Patients unfit for surgery and general anesthesia.
8. Cases with parents refusing the procedure.

Follow up:

All patients were followed up for at least 6 months post-operatively both clinically and audiologically to evaluate the effects of two different materials of ventilation tubes on the outcome of the myringotomy

Post –operative evaluation:

During the follow up visits, the following parameters were assessed:

1. The patency of the myringotomy site using the oto-microscope and tympanometery. Patients were seen every month to detect the time of closure.
2. the degree of hearing improvement using the tunning fork tests and pure tone audiogram.
3. occurrence of post-operative complications as:

- Rapid closure of myringotomy site.
- Recollection of fluid.
- Early dislodgement of ventilation tube.
- Post-operative otorrhoea "post-operative bacterial infection".
- Occurrence of permanent perforation.
- Conductive deafness.
- Recurrence of middle ear effusion.
- Post-operativeotomycosis "post-operative fungal infection" and obstruction of the tube (nonfunctional tube).

Post- operative audiological evaluation:

Pure tone audiometry was done at 3 months and 6 months post-operatively to evaluate the degree of hearing improvement. Tympanometry was done after extrusion of the ventilation tube and closure of myringotomy to evaluate the re-collection of fluids. Then all data were entered into a spread sheet and statistical analysis was performed to describe the response.

3. Results

The age of all candidates ranged from 5 to 15 years (mean+ SD = 7.9 +2.3) and were distributed in the following age groups (77.5%) aged less than 10 years and (22.5%) aged from 10 to 15 years.

Considering gender, 55% of children were males while females constituted only 45% of the studied sample. (Fig 3).

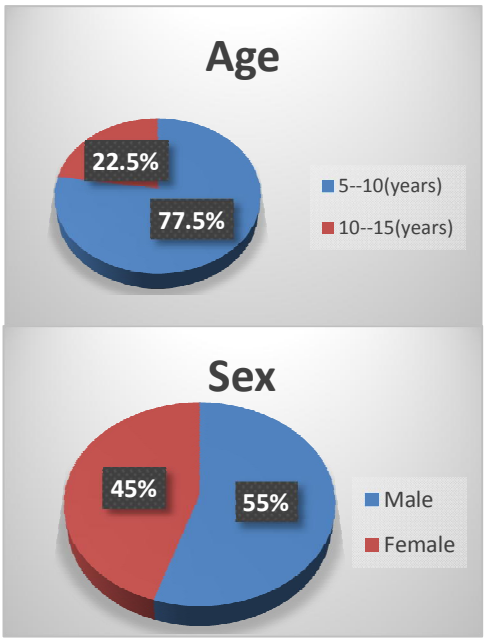

Fig. (3): Age and sex distribution.

Pre and post-operative subjective assessment:

Post-operative subjective assessment in both groups compared with the

Pre-operative assessment:

The main pre-operative complains of the patients and/or their parents are illustrated. All of the children complained of decreased hearing,55% complained of otalgia. Tinnitus was reported in 50%, speech problems were reported in 20%. Educational problems and poor balance were reported in 15% and 5% respectively (Table1).

Subjectively there was improvement in all pre-operative symptoms with variable grades. Hearing loss was persistent in 2.5% of ears with silicon tube whereas 5% of the ear with Fluroplastic tube still has hearing loss. Otalgia was reported in 4.55% in the ear with silicon tube and 9.09% still having otalgia in the

ear with Fluroplastic tube. Regarding the tinnitus by the end of the 6 months post operatively it was improved in all cases in the ear with silicon tube and 5% still having tinnitus in the ear with Fluroplastic tube. Speech problems, educational problems and balance problems were improved to the same degree in both types of ventilation tubes. It was found that 12.5% still having Speech problems, 16.67% still having educational problems and balance problems were reported in 50 % (Table 1).

Table (1): Descriptive and comparative statistical analysis between pre and post-operative subjective assessment.

Pre and post-operative subjective assessment:								
Complains	**Pre-operative**		**Post-operative**				χ^2	**p-value**
			Fluroplastic ventilation tube		**Silicon ventilation tube**			
	No (40)	**%**	**No**	**%**	**No**	**%**		
Decreased hearing	**40 A**	**100**	**2 B**	**5**	**1 B**	**2.50**	**147.556**	**0.000****
otalgia	**22 A**	**55**	**2 B**	**9.09**	**1 B**	**4.55**	**47.290**	**0.000****
Tinnitus	**20 A**	**50**	**1 B**	**5**	**0 B**	**0**	**23.145**	**0.000****
Speech problems	**8 A**	**20**	**1 B**	**12.50**	**1 B**	**12.50**	**10.602**	**0.000****
Educational problems	**6 A**	**15**	**1 B**	**16.67**	**1 B**	**16.67**	**6.641**	**0.036***
Poor balance	**2 A**	**5**	**1 B**	**50**	**1 B**	**50**	**6.023**	**0.045***

Table (2): Comparative statistical analysis for subjective assessment post-operatively between fluroplastic and silicon tubes.

Complains	**Pre & post**	**Pre-operative**	**Fluroplastic ventilation tube**
Decreased hearing	**Pre-operative**	**--------**	**--------**
	Fluroplastic ventilation tube	**0.000****	**--------**
	Silicon ventilation tube	**0.000****	**0.559**
otalgia	**Pre-operative**	**--------**	**--------**
	Fluroplastic ventilation tube	**0.000****	**--------**
	Silicon ventilation tube	**0.000****	**0.814**
Tinnitus	**Pre-operative**	**--------**	**--------**
	Fluroplastic ventilation tube	**0.000****	**--------**
	Silicon ventilation tube	**0.023***	**0.174**
Speech problems	**Pre-operative**	**--------**	**--------**
	Fluroplastic ventilation tube	**0.001***	**--------**
	Silicon ventilation tube	**0.000****	**0.05**
Educational problems	**Pre-operative**	**--------**	**--------**
	Fluroplastic ventilation tube	**0.000****	**--------**
	Silicon ventilation tube	**0.005***	**1.000**
Poor balance	**Pre-operative**	**--------**	**--------**
	Fluroplastic ventilation tube	**0.000****	**--------**
	Silicon ventilation tube	**0.000****	**1.000**

By using The Kruskal Wallis test, it was found that there is highly significant improvement in all symptoms post-operatively (Table 1). However, Manny Whitney test proved that is non-significant difference in the degree of improvement in both groups (Table 2).

Pre and post-operative hearing level in dB:

The pre-operative pure tone audiogram reported that 10 cases (25%) their hearing level ranged from 20-30 dB, 26 cases (65%) between 30-40 dB and 4 cases (10%) between 40-50 dB (Table3). Post operatively PTA showed that in the ear with fluroplastic tube 24 cases (6o %) their hearing level less than 10 dB, 6 cases (15%) ranged from 10-20 dB, 5cases (12.5%) ranged from20-30 dB, 3 cases (7.5%) ranged from 30-40 dB, and 2 cases (5%) ranged from 40-50 dB (Table3). Post operatively PTA showed that in the ear with Silicon tube 25 cases (62.5 %) their hearing level less than 10 dB, 6 cases (15%) ranged from 10-20 dB, 6cases (15%) ranged from20-30 dB, 2cases (5%) ranged from 30-40 dB, and 1cases (2.5%) ranged from 40-50 dB (Table3).

The Kruskal Wallis test showed that there is highly significant difference between pre and post insertion of ventilation tubes in hearing level by dB as showed in (Table 3). Concerning with comparison between silicone and fluroplastic tubes using Manny

Whitney test, there is non-significant difference in hearing level by dB (Table4).

Table (3): Descriptive and comparative statistical analysis between Pre and post-operative hearing level in dB.

Air hearing level in dB								
Hearing level	Pre-operative		Post-operative				χ^2	p-value
			Fluroplastic ventilation tube		Silicon ventilation tube			
	No (40)	%	No (40)	%	No (40)	%		
Less than 10 dB	0 ^{A}	0	24 ^{B}	60	25 ^{B}	62.50	6.611	0.037*
From 10-20 dB	0 ^{A}	0	6 ^{B}	15	6 ^{B}	15	6.611	0.037*
From 20-30 dB	10 ^{A}	25	5 ^{B}	12.50	6 ^{B}	15	46.708	0.000**
From30-40 dB	26 ^{A}	65	3 ^{B}	7.50	2 ^{B}	5	47.704	0.000**
From 40-50 dB	4 ^{A}	10	2 ^{B}	5	1 ^{B}	2.50	89.703	0.000**

Table (4): Comparative statistical analysis in hearing level post-operatively between fluroplastic and silicon tubes.

Air hearing loss	Pre & post	Pre-operative	Fluroplastic ventilation tube
Less than 10 dB	Pre-operative	--------	--------
	Fluroplastic ventilation tube	0.011*	--------
	Silicon ventilation tube	0.001*	1.000
From 10-20 dB	Pre-operative	--------	--------
	Fluroplastic ventilation tube	0.011*	--------
	Silicon ventilation tube	0.001*	1.000
From 20-30 dB	Pre-operative	--------	--------
	Fluroplastic ventilation tube	0.000**	--------
	Silicon ventilation tube	0.000**	0.502
From30-40 dB	Pre-operative	--------	--------
	Fluroplastic ventilation tube	0.000**	--------
	Silicon ventilation tube	0.000**	0.646
From 40-50 dB	Pre-operative	--------	--------
	Fluroplastic ventilation tube	0.000**	--------
	Silicon ventilation tube	0.000**	0.559

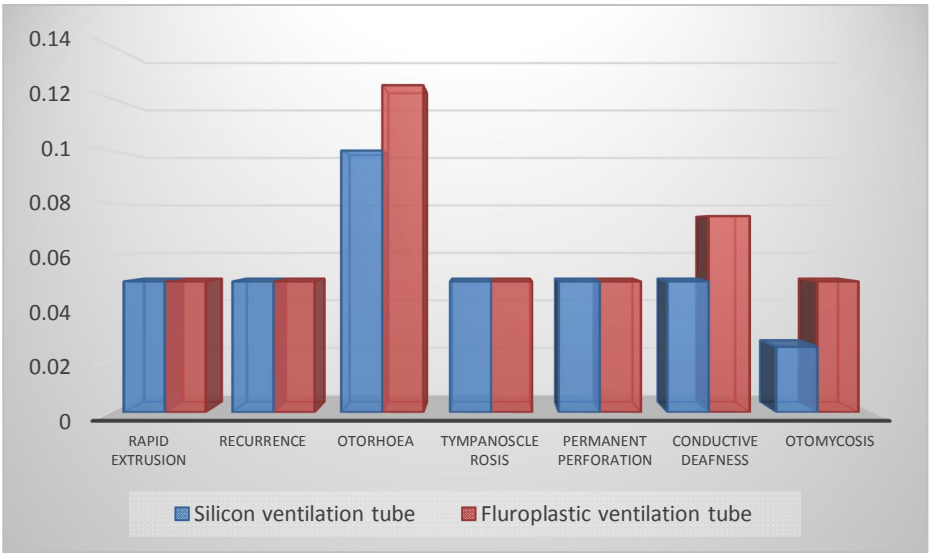

Fig (4): post-operative complications.

Post-operative complications:

6 months post-operative follow up reported the following complications in the right ear (with fluroplastic ventilation tube): rapid extrusion in the first month in 2 cases (5%), recurrence in 2 cases (5%), otorrhoea in 5 cases (12.5%), post-operative tympanosclerosis in 2 cases (5%), permanent perforation in 2 cases (5%), conductive deafness in 3 cases (7.5%) and lastly otomycosis was reported in 2 cases (5%) Fig (4).

6 months post operatively follow up of the left ear (with silicon ventilation tube) reported rapid extrusion of the tube in 2 cases (5%), recurrence in two cases (5%), otorrhoea in 4 cases (10%), post-operative tympanosclerosis in 2 cases (5%), permanent perforation in 2 cases (5%), conductive

deafness in 2 cases (5%) and otomycosis was reported in 1 cases (2.5%) Fig (4).

By using the proportion test it was found that there is non- significant difference between silicon tube and fluroplastic tube regarding the post-operative complications Fig (4).

Durability of the ventilation tube:

In the right ear (with fluroplastic ventilation tube) the tubes were extruded in 2 cases within the first 3 months and the tubes remained patent in 38 cases. From the fourth to sixth months post operatively another 3 tubes were extruded and the tubes remained patent in 35 cases Fig (5).

As regards, the left ear (with silicone ventilation tube) the tube was extruded in 1 case in the first two months and the tubes remained in 39 cases. At the third month another tube was extruded and the tubes remained in 38 cases. From the fourth to sixth months post operatively another 2 tubes were extruded and the tubes remained patent in 36 cases Fig (5).

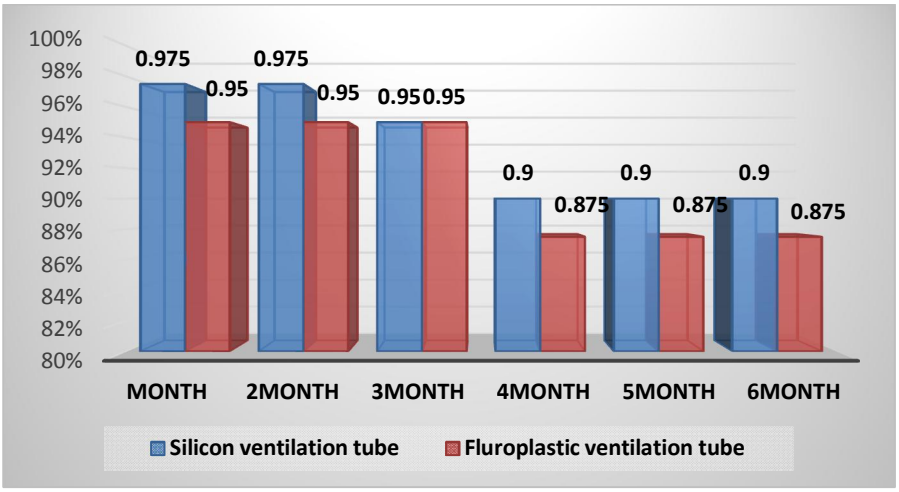

Fig. (5): Durability of the ventilation tube

The proportion test showed that there is non-significant difference between silicon tube and fluroplastic tube regarding the durability.

4. Discussion

The current study was done in two phases. The first phase which is baseline phase included baseline assessment of the children clinical data including complain, affected side, local and otoscopic examination findings and end by insertion a two different material of ventilation tube fluroplastic tube in the right ear and silicon tube in the left ear.

The second stage was following up the patients monthly for 6 months after surgical intervention to evaluate the clinical improvement and asses any complication.

The study results can be classified into:

- Baseline findings
- Follow –up findings

1-Baseline findings

This study include 40 patients have been proved clinically and audiologically to have bilateral chronic secretory otitis media type (B) tympanometery who treated by myringotomy and insertion of two different materials of ventilation tubes having the same shape and caliber.

The studied group was carefully selected according the criteria of inclusion and exclusion.

Socio demographic characteristics of the study sample.

The age of the selected patients ranged from 5 to 15 years with the mean age 16.75 year. Thirty one cases (77.5%) were between 5 to 10 years, it is mainly related to growth of adenoid at this period of age. This agrees with literatures where OME in children is mainly determined by the age of the child and the season of the year. The age prevalence is bimodal with the first and largest peak of approximately 20% at two years of age; and the second peak of approximately 16% at around five years of age. By the age of seven to eight years, the prevalence falls to around 5%. [9, 10] The adenoid can be identified from early gestation. Its growth continues rapidly during infancy and plateaus between two and 14 years of age. Regression of the adenoid occurs rapidly after 15 years of age in most children. The adenoid appears to be at its largest size by the age of seven; however, clinical symptoms are more common in younger children.[11]

In this study 55% of cases were males and 45% were females, this was comparable with another study which gave no significant difference in the prevalence of OME between both genders.[12] However; another

study demonstrated that males had a significantly higher proportion of OME; the proportion was greater in males (37.6%) than in females (29.8%) ($p<0.001$).[13]

Clinical assessment of the study children:

In this study, hearing loss was the main complain in 40 cases (100%), while tinnitus was reported in (20 %) of cases, ear pain in (55 %) of cases, speech problems in (20 %) of cases, educational problems in (15 %) of cases, poor balance and dizziness in 5% of cases this agree with Qureishi A et al,2014 who mentioned that OME is the most common cause of hearing impairment in children in developed nations,[14] and also agree with other author where Otitis media may be related to difficulties in speech and reading, delayed response to auditory input, limited vocabulary, and disturbances in attention.[15] It may also be associated with being less task oriented and less capable of independent classroom work.[16] Observational studies measuring caregiver reports suggest that school performance may improve after OME has been identified and treated.[17]

In this study, examination of the patients revealed presence of conductive deafness, opacity of the tympanic membrane in all patients, diminished drum mobility & retracted drum in vast majority of cases (90% & 95% respectively), and fluid level behind tympanic membrane were found in (10%) of cases and finally air bubbles behind tympanic membrane were found in (5%) of cases.

This is agree with **Robb PJ,2006** where otoscopic ear examination showed Loss of the light reflex, dullness, amber-gold colouration of the tympanic membrane because of middle ear effusion are all common findings when a middle ear effusion is present. The apparent more horizontal appearance of the malleus that is often seen, results from negative middle ear pressure drawing the long process of the malleus medially. Attic retraction or atelectasis of the tympanic membrane may be visible[18]

Also all previously mentioned results of the current study were coincident with those obtained by **Blaney SP et al 1999**[19] who mentioned that most of cases had air fluid and retracted ear drum. And also to some extent agreed with results obtained by Brawner Jt et al 2008. who recorded fluid level among 58.7% of the cases.[20] In **2000 Bulletin** proved that Middle ear effusions decrease the mobility of the tympanic membrane and the ossicular chain. This loss of mobility results in an average hearing loss of 20 to 30 dB. The diagnosis of otitis media can be confirmed by tympanometry and audiometry.[21]

In **1999 Takahashi H**, showed that Diagnostic and prognostic values of eardrum mobility were determined by pneumatic otoscopy in 37 patients (56 ears) having otitis media with effusion (OME). Eardrum mobility was impaired or lost in less than half of the ears (46.4%), while a tympanogram detected 77.8% of OME. In 27 of the 37 patients (42 of the 56 ears), aeration of the middle ear space was examined by CT and demonstrated that the presence or absence of aeration was significantly correlated with the presence or absence of eardrum mobility.[22] so Clinical practice guideline recommended using Pneumatic otoscopy as the primary method for diagnosing OME because reduced tympanic membrane mobility correlates most closely with the presence of fluid in the middle ear.[23] Even if bubbles or an air-fluid level are seen behind the tympanic membrane on initial examination, pneumatic otoscopy is confirmatory and can differentiate surface abnormalities from true middle ear effusion.

In this study, tympanometery were done to all cases, tuning fork tests and pure tone audiograms were done to older and reliable children mostly over 5 years old group to confirm the diagnosis and evaluate the pre-operative hearing state.

This is agree with most studies where combining otomicroscopy and tympanometry, the diagnostic precision is improved[24]. Also The American Academy of Pediatrics (AAP)/American Academy of Family Physicians (AAFP)/Agency for Healthcare Research and Quality (AHRQ) guideline on OME recommend that performance of tympanometry be optional for confirming suspected OME. But it should be considered as an adjunct to pneumatic otoscopy when the diagnosis of OME is uncertain. [25, 26]

Surgical intervention:

In our study we used two different materials of ventilation tubes having the same shape and caliber we put Fluoroplastic tube in the right ear in all patients and silicone tube in the left ear in all patients.

During surgery it was noticed that the manipulation on the Fluoroplastic material tube during insertion was better than silicone because the rigid material facilitates tube insertion and its nonstick characteristics may reduce adhesion formation and/or clogging on a another hand the Silicone Material was extremely soft, compliant, elastic extremely lubricious and vent tubes are easily compressed for insertion and removal.

2-Follow –up findings

In our study we followed up all patients one visit per month up to 6 months post operatively to detect any clinical improvement, evaluate hearing statue and early detection of complications this is agree with Isaacson and Rosenfeld devised clinical guidelines on grommet surveillance in 1996 in the US [27]. They recommended that otolaryngologists should perform the first post-operative follow-up review within 2 to 4 weeks, and further routine visits every 4 to 6 months until 6 to 12 months following grommet extrusion.

These recommendations were used in the American Academy of Pediatrics (AAP) guidelines published in 2002.[28]

In this study, post-operative complication of ventilation tube were rapid extrusion, recurrence, otorrhea, tympanosclerosis, permanent perforation, conductive deafness and otomycosis, this agree with most studies.[29, 30]

Our results showed that there is no significant difference between two different materials (fluroplastic or silicone) in the complications occurred post-operatively.

In our study the most common complication was otorrhea in fluroplastic and silicone tube (12.5% & 10%) respectively. This is agreeing with **Myer, 2001**[31] where one of the most common complications after tympanestomy tube insertion is otorrhea. **Gross et al**[32] reported that 10% to 29% of tubes will sometimes drain after they have been placed, whereas **Kinsella et al**[33] reported a rate of 1.67%, and Derkay et al(30) reported a 7.8% rate of otorrhea. However, otorrhea is not serious in most cases; almost all patients experience some degree of hearing loss and discomfort.[31]

Tympanic membrane perforation is the other complication has been reported in 5% of cases in both types and this is agreed with literature [34, 35]where the permanent perforation ranged from 4% to 32.6% of cases. **Kalcioglu et al** [36] reported the perforation rates for grommet and T-tubes as 4% and 14.3%, respectively. This complication might have occurred because of the longer duration of the tubes.[35, 37] the longer the tubes remained in place, the higher was the incidence of persistent perforation after tube removal. [11] **Iwaki et al**[38]reported that long-term tubes (ie, Goode T-tubes) showed significantly high perforation rates compared with the Shepard grommet. The perforation rate was higher in the spontaneous extrusion group than in the intentional removal group after T-tube treatment in the study of **Saito et al**.[34]

As we discussed before in our result the extrusion rate of both type was 2% so the material has no effect on the time of extrusion. However **Valtonen et al**[39] reported that The extrusion time of ventilation tube depends on its type.[39] Grommets tend to be extruded earlier, whereas Goode T-tubes tend to remain longer. [38]The mean intubation periods were reported as around 5.9 and 10.7 months, respectively, in the literature.[38, 40]**Valtonen et al**[39] reported ventilation time as 31.7 months for Goode-T-tubes. Other authors confirmed the time to extrusion is dependent on the diameter and shape of the inner flange. Most VTs with an inner flange diameter up to 2.5 mm will be extruded within 8 to 24 months.[41, 42] If the inner flange is wider or T-shaped and up to 12 mm, the time of function is prolonged to more than 2 years.[43]

Development of tympanosclerosis is one of the most common complications after insertion of a tympanostomy tube. In our study the percentage of tympanosclerosis was 5% and it is small percentage compared with 32 and 40.4% reported by **Kay et al**.[44] and **Johnston et al**.[45], respectively. Approximately 32 percent of TMs (range 7 to 64 percent) develop asymptomatic whitish plaques of calcium and phosphate crystals (tympanosclerosis) after tube extrusion. [44] The plaques may be localized or diffuse and are of uncertain etiology. Boys are affected more often than girls [46] and larger plaques are associated with multiple intubations [47]

Our results showed post-operative improvement in hearing loss, otalgia, Tinnitus, Speech problems, Educational problems and Poor balance with variable grades by using ventilation tubes in the treatment of otitis media with effusion and also showed that there is no significant difference when comparing the degree of improvement in both groups.

About improvement in hearing loss, Speech problems and quality of life our results agreement with **Richard, Rosenfeld and et al**[48] where Large, moderate, and small improvements in QOL occurred after surgery in 56%, 15%, and 8% of children, respectively. Physical symptoms, caregiver concerns, emotional distress, and hearing loss were most improved, but significant changes were also seen for activity limitations and speech impairment. Trivial changes occurred in 17% of children, and 4% had poorer QOL. And also agree with **Rovers** who said The primary benefits of tympanostomy tube placement are reduced prevalence of MEE resulting in improved hearing, improved patient and caregiver QOL,[49]and possible improved language acquisition through better hearing across the speech frequencies, binaural processing, and sound localization.[49, 50]Systematic reviews of RCTs consistently describe improved hearing in the first 6 to 9 months [49]following tube placement as well as improved children's QOL the initial 2 to 9 months following tube surgery.

In our study showed that there is no significant difference in the outcome on using ventilation tubes of two different materials even they have the same shape and caliber. This is agreed with **Mackenzie 1984** where The difference in material of polypropylene and teflon in these two grommets seemed to make no difference to their performance.[51]

However other author said that there is not enough evidence to determine if the design or material of VT has an impact on VT function.[52] because there is only 1 study investigated the effect of the VT material and the consequences for function.[42]

5. Conclusion and Recommendations

It was found that there is high significant improvement in all symptoms post-operatively by using both types of ventilation tube. Also it was reported that is no significant difference in the degree of improvement in both groups.

Also, it was found that there is no significant difference between silicon tube and Fluroplastic tube regarding the Post-operative complications.

Our study showed that there is no significant difference in the outcome on using ventilation tubes of two different materials even they have the same shape and caliber.

This study needs to be repeated on a larger number of cases and needs a longer period of follow up for better evaluation.

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