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Plastic Ventilation Tubes and Their Impact on Middle Ear Pathology

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Abstract: *Otitis and middle ear disease present high morbidity rates in spite of current medical treatment, especially in the younger population. Otitis media with effusion (OME) is a chronic disease that is often found in school age children. Its evolution, recurrence, complications and resolution still present a challenge to otologists. For some time, middle ear ventilation tubes were used for this pathology, thus assuring proper middle ear ventilation and higher disease resolution rates. In the current paper, we investigate the connection between ventilation tube usage, the materials out of which they are made, the techniques involved and how these factors may influence disease resolution rates.*

Keywords: *fluoroplastic, ventilation tube, otitis media, effusion, cholesteatoma*

1. Introduction

The chronic otitis media with effusion (OME) is defined by the persistence of the middle ear effusion for at least 3 months and consists of a challenge for ENT doctors to treat.

The first to introduce the use of plastic ventilation tubes for the treatment of chronic otitis media with effusion (OME) was Armstrong in 1954. The tube would ensure continuous ventilation of the middle ear, as well as proper drainage of the fluid located there [1]. The tube was made out of fluoroplastic, a highly resistant fluoropolymer. A fluoropolymer is a fluorocarbon-based polymer with multiple carbon–fluorine bonds. It is characterized by high resistance to solvents, acids and bases.

The great diversity of ventilation tubes regarding material, length, inside and outside diameter or means of placement has provided a background for extensive research. Ventilation tubes can be set in place for a short time, as the first treatment option with an extrusion rate of 6 to 18 months, whereas the long term ventilation tubes have an extrusion time greater than 2 years. The extended periods of ventilation associate an increasing rate of complications. Long term tympanostomy tubes are indicated in case of OME recurrence as a second option or in the case of ventilation problems of the middle ear, as in the case of persistent Eustachian tube dysfunction, this condition is especially relevant in young children [2]. The Armstrong Grommet, Paparella tube type I and the Shepard tube are ventilation tubes usually used for short periods. Representatives for long term usage are the Paparella tube type II, the Sheehy tube, the Reuter Bobbin tube and the Goode T tube. Some authors may consider the Shah tube useable for intermediate periods [3].

After their insertion, the natural evolution of ventilation tube placement is considered to be that of lateral displacement towards the external auditory canal without any need for surgical management. However, when taking into consideration the particularities of each patient and their individual history, one cannot rule out the risk of tube retention or early extrusion, as well as other complications such as chronic otorrhea, tube obstruction, the accumulation of granulation tissue around the tympanostomy site or inside the ventilation tube itself, retraction pockets, perforations of the tympanic membrane or even iatrogenic cholesteatoma following removal [4]. A promising type of insertion that has been lately taken into consideration is the subannular insertion of the ventilation tubes (SAT). SAT represents a good

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option of placement when the tympanic membrane is too thin to support the grommet or in case of large perforations or retraction pockets, as well as in cases of adhesive otitis, chronic Eustachian tube disease when there is a need for long term aeration of the middle ear to obtain the resolution of the background disease [5].

2. Materials and methods

In the current paper, we investigate the connection between ventilation tube usage, the materials out of which they are made, the techniques involved and how these factors may influence disease resolution rates.

2.1. Study inclusion criteria

We searched through the ScienceDirect database using key words such as “grommet cholesteatoma”, “tympanostomy tube cholesteatoma” and the PubMed database for “ventilation tube extrusion”, “ventilation tube quadrant”, “grommet extrusion rate”. Inclusion criteria were considered to be studies reporting data regarding ventilation tube (VT) type, time intervals between the insertion of the VTs and their absence from the tympanic membrane, whether by spontaneous extrusion or surgical removal, the presence of complications related to VTs such as recurrence of otorrhea, VT related tympanic perforations, retraction pockets, tympanosclerosis and even cholesteatomas.

2.2. Exclusion criteria

The exclusion criteria we most often employed was the lack of access to full-text articles, also excluding the majority of abstracts that could not provide reliable data regarding the types of tubes used or the timespan of usage. We also excluded studies that included patients with craniofacial abnormalities. The search criteria were not limited to a certain time and we included all translatable languages. We used related articles found in Pubmed and ScienceDirect for their list of references to identify further relevant articles for the subject and this led to the extension of the search to Researchgate and DeepDyve for further full text articles.

3. Results and discussions

3.1. Ventilation tube placement

Previous recommendations regarding the placement of VTs avoided the PSQ (posterior and superior quadrant) because of its vicinity to the incudostapedial joint, the main placement of the tube in the AIQ (anterior and inferior quadrant) is regarded as first intention followed by placement in the ASQ (anterior and superior quadrant) for patients who need prolonged aeration of the middle ear. April et al conclude that the importance of prolonged ventilation should rely mainly on the design of the tube and not so much on its placement, as they encountered equal lifespans for VTs in a study conducted on 16 patients. An equally long time before extrusion was discovered for both types of placements (ASQ and AIQ) when type 1 Paparella tubes were used [6, 7]. The Paparella tubes used were made out of silicone. Silicone is used in some ventilation tubes for its many useful characteristics that include low chemical reactivity, low toxicity, non-stick properties and its unfriendliness towards microbiological growth. Gibbs and MacKenzie presented no difference in the lifespan of tubes inserted in the anterior quadrants as opposed to those inserted in the PIQ as cited by literature, disregarding the ease for the anterior VT positioning [6].

Tube placement in the ASQ can imply great effort depending on the external auditory canal configuration even though VT placed in this quadrant are theoretically expected to be retained for a longer time because of epithelial migration patterns, there is no significant difference between the lifespan of VTs in the superior versus the AIQ, with a mean time before extrusion of 12 months, respectively 12.8 months [3]. Walker’s conclusion on the matter pleaded towards greater importance given to the type of tube used, rather than the tympanic quadrant chosen for its placement when prolonged ventilation is necessary [3]. Silicone seems to be well tolerated in most patients and does not generate high extrusion rates.

Assessing the lifespan and placement of 3 tube types, Shepard, Reuter Bobbin and Polyethylene-90, the Shepard tube showed a significant difference when placed in the ASQ and the AIQ, with better function in the ASQ of the intact tympanic membrane while the Reuter tube functioned best in the IQ (inferior quadrant), and in the AIQ in cases which had previous tubes inserted [8]. In both normal or modified TM (tympanic membranes), the Reuter Bobbin tube lasted longer in place, with no important difference when placed in patients with tympanosclerosis [8]. The Reuter Bobbin tube can be made out of titanium or fluoroplastic, with both materials being well tolerated by patients.

3.2. Subannular ventilation tube placement

For the patients with chronic middle ear disease that require constant ventilation, VTs can be inserted in more than one position, the most frequent first option being the placement through the tympanic membrane. Sometimes, the tympanic membrane can suffer extensive damage ranging from small perforations, to larger ones, or even atrophy and damage to such extent, that it disqualifies as a good recipient for further tympanotomies.

Taking into account the extended need for appropriate middle ear ventilation in patients with chronic ear disease, in some cases, the proper treatment after multiple trans-tympanic ventilation tube insertions is considered to be the use of subannular ventilation tubes. An important aspect of the subannular VTs usage is the position of insertion, as the choice is based on the present status of the tympanic membrane. Tubes can be inserted in the anterior and posterior quadrants, the posterior wall of the external auditory canal or the posterior and inferior annulus, or the anterior part of the annulus [9]. The anterior annulus seems to remain unaffected in patients with chronic ear disease and in those that underwent mastoid surgery [10], as some of the techniques require a canal wall down type.

The first to describe an alternative technique for VTs insertion through a tunnel between the annulus and the external auditory canal epithelium was Simonton in 1968 [11, 12]. This VT placement can be kept in place longer and without being affected by the centrifugal healing pattern of the tympanic membrane.

We have identified a study assessing the subannular insertion of VTs in the posterior and inferior quadrant. The authors' choice was a long term usage tube - a Goode T tube (made out of silicone) - inserted in the external auditory canal where a tunnel was drilled beforehand. A tympanomeatal flap was also used in this technique [13]. Most papers approaching the subannular insertion of ventilation tubes consider the use of Goode T tubes most appropriate, given the advantages of the silicone such as safety, little TM damage and low complications rate [5] The low complication rate seems to correlate directly to the tolerance towards silicone and its antimicrobial properties.

The age group between 5 and 9 years of age is considered most prone to infections and thus associating frequent Eustachian tube dysfunction and the need for proper middle ear ventilation [14]. Children in this group also have the most SAT insertions as shown by Yang et all, Cloutier et all, while Saliba et all present the average age for the SAT insertion to be 7,4 years old [5, 9, 13].

Cloutier et all confirm that the long term usage of SATs, highlighting the lifespan difference between the fluoroplastic tubes and the Goode T tubes, (17,8 months compared to 23.8 months) correlates with the need for reintervention, as shown by studies [11, 14]. The lifespan for SATs has a variability between 13.4 months in the O'Hare's study and 41.3 months in Yang's paper, with a mean lifespan of 35 months presented by both studies conducted by Saliba and Cloutier [5, 9, 10, 13, 14]. Silicone tubes seem to reside more in place than fluoroplastic ones.

The eardrum insertion of the SATs may differ, as Yang, Cloutier and Saliba used the posterior part of the annulus for insertion, whereas O'Hare and Elluru preferred the anterior annulus [5, 9, 10, 13, 14]. Considering the average lifespan of the SATs, O'Hare highlighted the minimal time for SATs to reside in place was 13 months, most probably because of the short follow-up period [10]. Considering the outcomes presented, 16 out of 19 patients presented a functional SAT and an aerated middle ear and no retraction of the tympanic membrane in O'Hare's paper while Elluru presented aeration of the middle ear in 84% of patients, patent T-tube in 89% of patients and complications in just 29%. The most frequent complications were posterior tympanic membrane retraction, thus highlighting the possibility of better anterior middle ear ventilation supported by the anterior placement of the SATs [9, 10]. As shown in the studies, the retraction was reversible in most cases, with the surgical removal of the VT.

Comparing the use of the posterior quadrant for SAT placing and multiple anterior quadrant TTTs placements, most of the SATs followed previous attempts of TTTs placements, more than 60% of SAT patients receiving at least 2 TTTs before having the SAT inserted [5]. When considering the lifespan of all the tubes, the average in-place duration of 35 months for SATs and 7 months for TTTs, the difference between the two is significant ($p<0.001$). The early extrusion of the trans-tympanic tubes highlights SATs as possible solutions to the need for long term ventilation and prevent unwanted events such as early extrusion and the need for early replacement [5]. Due to their materials and the technique involved, SATs can be maintained in place for about 5 years or until the age of 12, when aeration is probably unnecessary. Because of their shape and resistance towards natural extrusion their removal is carried out by the ENT doctors in 11% of cases, in comparison to only 5% of cases for the TTTs [5].

The most common complication associated with the Goode T tubes was otorrhea. Half of the suppurative complications of tube placement occurred earlier for the TTTs, 19 months after their placement compared to 72 months for the SATs group [5]. Luminal blockage by discharge and granulation tissue also appeared earlier in the TTTs group (20.8% at 9 months versus 13.7% at 48 months, respectively and 75% at 15 months versus 25%). Discharge blockage is considered to be related to the recurrence of otorrhea. Other noteworthy complications are iatrogenic cholesteatomas following the insertion process for subannular grommets [5].

3.3. Complications associated with ventilation tubes - tympanic membrane perforation

In the case of tympanic membrane perforation following tube extrusion, the closure is determined by the migration of the epithelial layer, followed closely by the fibrous and the mucosal layers to patch up the perforation [12]. Permanent tympanic membrane perforations can be directly associated with the time the ventilation tube was present, the perforation rate increasing from almost 10% at 6 months, to around 40% at 18 months [15].

The majority of VTs are retained in place in the anterior and superior quadrant, associating a TM perforation chance of 1-15% [16]. Long term placement tubes (Paparella type 2, Richards modified T tube, U tubes) are more likely to associate a persistent perforation, especially in patients older than 10 years according to Brown and Behar [16]. More than one previously inserted VT and tympanosclerosis doubles, respectively triples, the risk of persistent perforations [16]. It goes without saying that the bigger the perforation's diameter, the bigger its chances of persistency. Brown also highlights that perforations post VTI larger than 10% of the entire diameter of the TM are more likely to lead to persistent perforations five times more often [16]. The rate of persistent perforations associated with short term VT placement (Armstrong) is around 6.6%, considerably lower than the 20% rate associated with the long term ones [16].

The perforation rate for short term placement tubes remains under 10%. The Shepard tube placed in the anterior and inferior quadrant yields a 5.5% perforation rate in Fior's study, perforation that healed during follow-up. The rate is much lower in Walker's study with only 1 tube out of 212 reported for TM perforation [3, 17].

3.4. Complications associated with ventilation tubes - tympanic membrane retraction

An important entity that Buckingham and Ferrer also considered that may lead to cholesteatoma formation is represented by retraction pockets that require aeration of the affected middle ear [18]. Taking into account the usage of grommets to ensure proper middle ear aeration and thus preventing the negative middle ear pressure, tympanic retractions represent one complication that should be taken into account after the grommets' extrusion or removal, as an important aspect of the follow-up [19].

3.5. Complications associated with ventilation tubes - Cholesteatoma

There is great debate whether the presence of cholesteatoma in patients with ventilation tubes can be directly attributed to their use or not, as almost 8% of responses in Armstrong's study found a direct correlation between the two [20]. Buckingham supported the theory of grommets associated cholesteatoma formation based on finding the promontory covered in shredded epithelial layers [21]. Even though no cholesteatoma was found during the study conducted by Hughes, it highlights the presence of 3 attical cholesteatomas after VT insertion and extrusion [22].

Considering a 10-year follow-up as a sufficient long period of time, Fior and Veljak reported no cholesteatomas associated to tympanostomy site in the use of the Shepard grommet in the anterior and inferior quadrant [17].

Cholesteatomas can develop secondary to a malpositioned VTs or it can develop more or less in parallel with a partially functioning grommet, such as the case highlighted by Kokko [23], associating 2 attical cholesteatomas non-related to VT placement, 2 situated postero-superiorly of pars tensa: one VT-related cholesteatoma and one non-VT related [23]. It seems that placing the VT improperly along the TM margin increases the risk of perforation and cholesteatoma with no clear involvement related to the materials used [23].

3.6. Complications associated with ventilation tubes - extrusion time

Based on current literature, the extrusion time for VTs is difficult to correlate with risk factors. As ventilation tubes are usually inserted for improving the middle ear aeration and for the reduction in discharge, there is no apparent correlation between the presence and/or viscosity of the effusion and the time of VT extrusion [24].

When assessing the extrusion time for ventilation tubes, the period was calculated as half the timespan between the last moment when the tube was in place and the first consult when the tube wasn't identified in the TM [25].

There is support towards the lack of significance of the insertion quadrant of the VT and its extrusion time, at least for the Paparella type I [7], and the Shah grommet type [26] when assessing the ASQ and the AIQ insertions [7, 26].

The surgeon's experience might be a factor regarding the interval before extrusion, both Hussain and MacKenzie reported a longer period before VT extrusion when the Shah and Shepard tubes were inserted by senior staff members. An average of 11.72 months versus 9.34 months for the Shepard tube and 13.03 months versus 12.97 months for the Shah tube were compared for senior versus junior surgeons. In MacKenzie's report, at one-year evaluation, 11 out of 12 inserted tubes were present versus 1 tube out of 46 for junior staff members [6, 27, 28].

3.7. Spontaneous versus surgical extrusion of the ventilation tube

In Fior and Veljak's study, 92.3% of the Shepard tubes from the AIQ were reported to be spontaneously extruded after an average period of 9.8 months and only 8% of them required surgical removal by the specialist doctor [17]. Comparing the Shepard tube and the Goode T- tube, the short term tube extrusion rate is much faster with an average lifespan of 160.5 days, in comparison to 274.1 days for the long term tubes [29].

Going further and comparing the average duration before extrusion for 3 tube types (Shepard, Shah, Sheehy tubes) positioned in the ASQ and AIQ, there was no statistical difference for both quadrants, the life span increased as expected to short, medium and long term tube usage [3]. For these types of tubes, extrusion rates did not correlate with positioning, but rather with their materials. Fluoroplastic tubes seem to be well tolerated and retained despite their placement. Gibb and MacKenzie concluded on the Sheehy ventilation tube as being a favorite all-rounder because of its easy to insert design and also being a safe choice for up to 24 months [6].

3.7. Otitis media with effusion recurrence

The recurrence of chronic otitis media with effusion was reported to be higher when the Goode T-tube was removed earlier than 12 months. The recurrence rate was different, lowering over time. At 6 months, the recurrence rate was around 20%, at 12 months around 10%, and at 24 months, less than 5% [15].

Discharge has been presented as being a normal postoperative occurrence, with a 1.8% recurrence rate for Shepard's short-term placement tube, in comparison to 15.7% discharge recurrency rate during follow-up of up to 15 years [17]. When compared with the use of the Goode T- silicone tube, the Shepard grommet associates a 63.6% rate of recurrence for post extrusion discharge, with no significant difference to the long term T tube (72.8% recurrence) [29]. In contrast, Yaman et al conclude that a lower recurrency rate for OME is associated with a longer life span of the Shepard tube, showing a 36.54% recurrency after 6 months following tube extrusion. Considering a general rate of recurrence of 20.7% for OME, the primary school age group associated the highest rate, with no significant modifications of this rate after VT extrusion [30]

3.8. Tympanic membrane Atrophy

The usage of the Shepard tube is associated with a 5.5% rate of tympanic membrane atrophy [17], which can be considered as a preliminary state for future tympanic retraction pockets or even perforations. It is unclear if prolonged use of fluoroplastic materials is more likely to cause tympanic atrophy as opposed to silicone materials. Further studies are required in this direction, as few articles target this aspect.

3.9. Disease resolution

The timespan of the follow-up and the age of the patient are both very important, as the time needed for the middle ear mucosae to heal is considered different depending on the host's immunological status and its previous damage. A 2 to 3 year period is the timespan needed by the middle ear mucosal layer to recover after a chronic secretory active otitis media, as the poorest results were seen in patients during the first 2 to 3 years of follow up. Using the TTTs in patients under 7 years yielded resolution in 80% of the cases, most probably given the shorter period of mucosal aggression and the type of existing effusion. In children with chronic OME the outcome is poorer than in those with only Eustachian tube and middle ear ventilation dysfunction. 80% of patients with chronic OME, at some point, underwent bilateral TTTs insertions [30].

Most patients with an average age of 3 that received short term AIQ VT insertions (for example Shepard's fluoroplastic tube) displayed a rate of resolution considered satisfactory in more than half of treated cases. Fior reports better resolution rates of 67.6% at 5 to 15 years post grommet extrusion when fluoroplastic materials are used [17].

4. Conclusions

Our extensive literature review concludes that silicone is still a good "all-rounder" material when it comes to its biological uses; the short-term placement VTs made out of it are well tolerated and their extrusion is not influenced by the material type or position of its trans-tympanic placement. However, should a longer ventilation time be necessary, a subannular VT insertion is to be looked into as long term silicone VTs may offer the best middle ear aeration in this case. Factors that influence the success rates of this tubes' usage also include the experience of the operating surgeon.

For the subannular placement, the anterior part of the annulus seems to offer a better choice of placement, and, disregarding the material used (silicone, titanium or fluoroplastic) this technique implies a certain rate of cholesteatoma formation.

Fluoroplastic materials hold their own right, being better tolerated than polyethylene tubes, and also presenting good success rates when placed under the tympanic annulus. The risk of tympanic membrane perforation doesn't seem to be linked to the type of material used but a history of previous ventilation tube placements, especially if trans-tympanic, heightens this risk. Fluoroplastic materials also seem to present the best OME resolution rates, but we consider more studies are needed to be able to link OME resolution rates to the material used in VTs.

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