Chapter 167: Tympanic Membrane - Tympanostomy Tubes

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The insertion of tympanostomy tubes is the most common operation performed in the USA; an estimated 2 million tubes are inserted each year (Paradise, 1977). The economic impact is staggering.

This chapter focuses on historical perspectives, surgical indications, operative considerations, and complications of the surgery. Measures to minimize the complication rate and maximize the effectiveness of the operation are stressed. The disease processes that underlie the surgical indications are only touched on here, since they are discussed in greater detail in Chapters 156 and 157.

Historical Perspectives

Recognition of otitis media with effusion (OME) and attempts to restore hearing by manipulating the tympanic membrane and middle ear date back to the seventeenth century. Politzer (1981) credited Riolan the Younger, in 1649, as the first physician to intentionally lacerate a tympanic membrane to restore hearing. In 1799 Home performed a study comparing the anatomy of the elephant and human ear (Hore, 1800). Cooper was present at the lecture and became interested in investigating the human ear (Cooper, 1800). The following year, he reported to the Royal Society of London that when he punctured the tympanic membrane and removed the fluid, his patient's hearing immediately improved (Cooper, 1801). The results did not last long, because the perforations healed within a few days and the conductive loss returned when the fluid reaccumulated. Toynbee (1868) mentioned Cooper's treatment but preferred to treat OME with bichloride of mercury and leeches behing the ear. Ballin (1926) also noted that myringotomies decreased the incidence of OME and that the perforations healed rapidly.

Politzer, in 1860, was the first individual to place a hard rubber tube through the tympanic membrane. The tube, designed with three flanges and a groove to secure it in place (Dalby, 1873), was amazingly similar to current designs. Dalby worked with the Politzer tube and noted its effectiveness in treating OME; however, the tubes very often were quickly extruded (Dalby, 1873). Investigators then studied other mechanisms of maintaining persistent perforations as the best method for treating OME. Voltolini (Burnett, 1886) encircled the malleus with a gold ring; however, the perforation did not persist. Politzer described several attempts to maintain permanent perforations (Ballin, 1926). In 1879 Kellel detached the anulus tendinosus without significant success. In 1896 Miot excised the entire tympanic membrane and ossicles, which indeed resolved the problems with OME and progression to a cholesteatoma; such a procedure, however, is inappropriate by current standards. During the first part of this century, physicians continued to concentrate on effecting persistent perforations, experimenting with techniques using electrocautery and chemical cauterization, but were unsuccessful.

Armstrong (1954) reported a then-new treatment for chronic secretory otitis media. He place a No. 9 polyethylene tube through the tympanic membrane and found that it functioned well as long as it was open and in place. He noted that the problem was early extrusion. Over

the next several years a number of clinicians modified the tube in attempts to make it function longer, and a bewildering number of different tube designs currently exist.

Indications

Tympanostomy tubes have been used to treat a diverse group of diseases and conditions. Several of the most common are found in the following list:

1. Chronic (persistent) OME

2. Recurrent acute otitis media (rOME)

3. Acute OME (AOME) with complications

4. Conductive hearing loss secondary to fluid with additional handicaps

5. Tympanic membrane atelectasis (retraction pocket)

6. Hemotympanum without spontaneous resolution

7. Cholesteral granuloma

8. Patulous eustachian tube.

The major indication for the operation involves chronic OME. The classification of OME has frequently changed, but that developed by the Ad Hoc Committee on Definition and Classification of Otitis Media (Bluestone, 1980) has become the mose widely accepted and is recommended. It describes OME by duration (acute OME lasts up to 21 days, subacute OME lasts 22 days to 8 weeks, and chronic OME lasts longer than 8 weeks) and by type of effusion (serous, purulent, or mucoid). Most physicians consider chronic otitis media with effusion (COME) to be present when the middle ear effusion has existed for 10 to 12 weeks. This time period is based on studies of the natural history of OME. Purulent otitis media with effusion usually evokes the symptoms clasically associated with acute otitis media; the fluid may rapidly resolve or persist for a variable length of time. Teele et al (1983) have shown that, after the onset of a single acute infection, effusion persists in 20% of children for 2 months and in 10% for 3 months. Casselbrant et al (1985) found that around 80% of preschool children with OME in day-care centers cleared their effusions within 2 months. Children without resolution at 2 to 3 months have chronic OME; having not cleared within the first few months, they have a low rate of resolution in the following months.

Efficacy in treating COME with tympanostomy tubes was shown by Mandel et al (1989) in a prospective, randomized trial of infants and children with OME refractory to medical therapy after 2 months' duration. Myringotomy and tube placement were compared to "myringotomy only" and "no surgery" groups. They found that the group with myringotomy and tube placement had more disease-free time and better hearing than either of the other groups. Myringotomy only had the same outcome as the no-surgery group. Gates et al (1987) found similar results when comparing myringotomy only with myringotomy and tube (with or without adenoidectomy). Subjects who had tube placement fared better regarding

effusion-free time and hearing while the tube was functional when compared with subjects who had myringotomy alone. The benefit of tube placement is, however, apparently limited to the time period that the tube is functional. Tympanostomy tubes are used to treat COME, in the hope that improvement in the predisposing factors leading to COME will occur by the time the tubes become nonfunctional. Some of these predisposing factors seem to be improved by adenoidectomy (Gates et al, 1987). Comparison studies of tympanostomy tubes versus medical therapy for COME have not been specifically undertaken; however, both Gates et al (1987) and Mandel et al (1989) required that subjects fail to respond to medical oral antibiotic therapy before enrollment into their studies.

Acute OME may be recurrent with complete resolution of the effusion between episodes. Intermittent eustachian tube dysfunction is the probable cause of rOME, and these patients are good candidates for prophylactic antibiotics (Bluestone and Stool, 1983; Liston et al, 1983; Maynard et al, 1972; Perrin et al, 1974). Prophylactic antibiotics are particularly useful in the late winter and early spring, when respiratory tract infections are common. When antibiotics fail or when parents are opposed to long-term antibiotics, tubes may reduce the number of recurrent infections (Gebhart, 1981); however, tubes may extrude before the recurrent otitis media has resolved. In these patients adenoidectomy is beneficial (Paradise et al, 1980). Thus patients who develop recurrent otitis media after tube extrusion and fail to respond to antibiotic prophylaxis frequently receive adenoidectomy or reinsertion of tympanostomy tubes or both.

Recurrent OME may also represent reinfection of a sterile COME. These children probably have persistent eustachian tube dysfunction from a variety of causes and are not likely to respond to prophylactic antibiotics. Poor eustachian tube function may result from pliable cartilage (Beery et al, 1975) or an anatomic abnormality of the skull base preventing the function of the tensor veli palatini muscle. Intrinsic eustachian tube obstruction exists with respiratory tract infections or allergy (Bluestone et al, 1977), whereas extrinsic obstruction may result from excessive adenoid tissue or nasopharyngeal tumors (Bluestone et al, 1972, 1975). Children with compromised local defense mechanisms may also have persistent effusion, as is seen in those with the immotile cilia syndrome (Fischer et al, 1978). Children with COME or rOME constitute the majority of indications for tympanostomy tube placement.

Ventilating tubes are not indicated for individuals with acute otitis media (AOM) except when complications arise. Complications of AOM (such as facial paralysis, vertigo, and meningitis) are treated with tympanocentesis or myringotomy for the removal of bacteria for culture. If a tube is placed in these situations, many clinicians favor the placement of a grommet for short-term ventilation and drainage and the introduction of antibacterial drops into the tympanum.

Persistent effusion may be harmful in several ways and therefore is an indication for tube placement. Recurrent infections have already been mentioned. Structural changes in the tympanic membrane and ossicles constitute another population group treated with tympanostomy tubes. Buckingham (1982) demonstrated the progression of negative pressure and middle ear effusions to pars tensa cholesteatomas and their reversal by tympanostomy tube insertion. Improvement of middle ear atelectasis with ventilating tubes is well known to otolaryngologists - head and neck surgeons. Erosion of the long and lenticular processes of the incus may be associated with ossicular and tympanic membrane contact. Although clinical

research studies of this phenomenon are lacking, the clinical evidence favoring tympanostomy tubes to reverse this situation is strong.

Hearing loss is another important indication for tube placement. Three relevant points are (1) chronic, bilateral, mild to moderate conductive hearing loss is educationally damaging (Holm and Kunze, 1969; Sak and Ruben, 1981); (2) OME causes such hearing losses (Bergman, 1979; Wiederhold et al, 1980); and (3) the conductive hearing loss of OME improves with functioning tympanostomy tubes (Bergman, 1979).

Teele et al (1990) studied the effect of COME during the first 3 years of life by studying children prospectively from birth until age 7 years. They found that as middle ear effusion time increased from less than 30 days to greater than 130 days the "scores on test of cognitive ability, speech and language, and school performance" were lower. The adjusted mean full scale WISC-R scores were 113.1 for those with the least time of COME, 107.5 for those with moderate time, and 105.4 for those with the most time (> 130 days). Mathematic and reading scores were similarly affected. They also found that COME time after 3 years of age was not a significant factor in predicting the test scores.

A comparison of medical therapy (6 months of sulfisoxazole) versus tympanostomy tubes was performed in a prospective trial for COME by Bernard et al (1991). They found a higher rate of successful therapy in the surgical group at 6, 12, and 18 months. Although better hearing was experienced by the surgical group at 2 and 4 months, no difference in hearing was found between the two groups after that. Retreatment was also more common in the medically treated group. The tympanostomy group had a statistically greater rate of myringosclerosis. (See section on myringosclerosis later in chapter.)

By itself, chronic hearing loss from OME is an indication for tympanostomy tube placement under certain circumstances. It is particularly compelling in children with multiple handicaps (for instance, mental retardation and visual impairment) or with an existing sensorineural hearing loss and in those who are functioning poorly in the current educational setting.

Certain other conditions have been treated less successfully with tube placement. Idiopathic hemotympanum and cholesterol granuloma appear to be related to chronic eustachian tube dysfunction. Treatment with tympanostomy tubes has not been universally successful. Nor are symptoms associated with a patulous eustachian tube necessarily relieved with tube placement.

Operative Considerations

Neel et al (1977) showed that ventilating tubes bypass and do not alter the underlying eustachian tube dysfunction. Tubes function only when they are in place and patent. If they become persistently occluded or extrude, the effusion may recur. Attempts to prevent extrusion have led to a number of different tube designs and placement strategies.

The passage of water through the tube and into the middle ear can cause water contamination during normal bathing, showering, and swimming. The mechanisms to prevent this contamination include exclusion of water from the external auditory canal by various

occlusive techniques (petrolatum-impregnated cotton, Silly Putty, custom-designed ear molds, bathing caps, and so on) and the use of tubes that impede water penetration. Longer tubes were designed for this purpose and are clearly more effective at it than is the grommet, or short, tube. However, when otorrhea develops, the longer tube prevents introduction of topical antibiotics through the tube into the middle ear. In addition, when otorrhea occurs, inspissated purulence frequently occludes the lumen of the longer tube. The shorter tube does not impede water contamination, but it allows the physician to use topical antibiotics to treat otorrhea and even to soften inspissated purulence, allowing mechanical cleaning of the tube lumen.

In the belief that water contamination causes otorrhea, researchers have developed semipermeable tubes. Cantekin and Bluestone (1976) initially found semipermeable tubes to be satisfactory; after evaluating 41 ears, however, Cantekin et al (1977) found that 76% were occluded at some time while the tubes were in place. They also found that 24 of these ears had recurrent OME while the tube was in place. On the basis of these results, they did not endorse the use of semipermeable tubes. Levinson et al (1982) found a semipermeable tube satisfactory if it was not used in patients with "glue ears" and if systemic antibiotics were used for 5 days after the tube was placed. Other authors have reported more successful trials with semipermeable tubes. Bailey (1980) reported failures in only 5 out of 29 cases, and Plotkin (1981) reported a 5.5% incidence of otorrhea and a 2% incidence of serous otitis media. None of these authors state whether their patients were allowed to swim in lakes or rivers. Despite the above reports, most otolaryngologists seem to prefer standard tubes to semipermeable tubes.

To prevent early extrusion, the physician may also choose a tube with large medial flanges. The Per-Lee tube (Per-Lee, 1969) has an extremely large flange and almost requires a tympanostomy for proper positioning; it is associated with a 25% incidence of perforation (Holt and Harner, 1980; Per-Lee, 1981). The Shepard, Donaldson, Reuter Bobbin, and polyethylene tubes last less than 10 months (Leopold and McCabe, 1980). The Goode T-tube (Goode, 1983) is Silastic and can be used as either a short-term or a long-term tube. When it is used as a short-term tube, the medial flange is trimmed to approximately 2 mm in length, and the shaft is cut to 4 mm. Recently grommet T-tubes have been produced, which decrease the chance of the tube falling into the middle ear. The T-tube functions an average of 33 months and the Armstrong long-acting tube an average of 22.7 months (Armstrong, 1983). Although Goode (1983) reported only a 3% incidence of perforation, others have reported rates as high as 12% (Weigel et al, 1989). In a comparison of the Shepard grommet, Armstrong beveled tube, Reuter Bobbin tube, and Goode T-tube, the Goode T-tube remained in place the longest but had the highest rate of otorrhea and residual perforation (Table 167-1). Various tubes designed to remain in the tympanic membrane longer are commercially available, but clinical experience has indicated that persistent perforation rates go up as tubes remain in the tympanic membrane longer or as the outside diameter of tubes increases.

If the tube is to function longer, it must be not only designed properly but also positioned properly. Stinson (1936) found clues to the premature extrusion of a foreign body in the tympanic membrane; however, that information went essentially unrecognized for many years. Turner (1967) found that the epithelium of the anterosuperior quadrant of the tympanic membrane migrated primarily toward the anterior anulus. The epithelium of the anteroinferior quadrant and of both posterior quadrants migrated toward the posterior border of the tympanic membrane. However, he failed to use this information in placing ventilating tubes. Armstrong

(1983) demonstrated that the tubes placed in the anterosuperior quadrant close to the anulus were retained four times longer than tubes placed in the anteroinferior or posteroinferior quadrants. He preferred a radial incision, which destroys less of the lamina propria. Some authors favor a U- or V-shaped incision, but the tip of the flap receives a poor blood supply, resulting in necrosis and a larger perforation than would otherwise occur (Armstrong, 1983).

When a child is to receive the first set of tubes and is not in the high-risk category, a shorter-acting grommet with a good-sized medial flange placed in the anteroinferior quadrant is preferable. The tube stays in place for 6 to 12 months, and otorrhea can be adequately treated with topical antibiotics. If an additional set of tubes is necessary or if the child fits into the high-risk category, a longer-acting tube may be placed in the anterosuperior quadrant. Other factors may be considered when placing tubes. Some physicians prefer the Armstrong beveled tube or the Pope tube; these tubes allow easier postoperative evaluations because the tube is designed to line up the tube shaft with the ear canal. This allows the physician to more easily view the tube shaft to see if the tube is plugged, assess the middle ear mucosa, or remove debris in the tube shaft. Very small ear canals such as those encountered in premature infants or Down's syndrome patients may required use of minitubes such as the mini-Shea or mini-Shah tubes. These tubes can be more readily placed through tiny canals; the disadvantage seems to be relatively early tube extrusion when compared with more standard tubes.

Complications of Ventilating Tubes

Otorrhea

Otorrhea is the most frequent complication associated with tubes. The occurrence rate of otorrhea varies from 15% to 50% of patients, with most investigators citing figures around 20% depending on the tube studied and the patient population.

The occurrence of otorrhea weeks or months after tube insertion probably results from either water contamination through the tube lumen or development of a new episode of AOME. Water contamination can be prevented or minimized by parental education and compliance with water precautions. Otorrhea from new episodes of OME may be prevented by concomitant use of prophylactic antimicrobial agents. It is difficult to ascertain from the literature which of the two mechanisms occurs more frequently, but the incidence of otorrhea increases with the use of longer-acting tubes. The increased duration of function of those tubes allows more time for new episodes of OME as well as a greater possibility for external water contamination.

The mechanism of otorrhea does seem to depend on age. Clinical experience over the last decade has led most physicians to place strict water precautions on older children and adults with tubes. These same physicians allow loose or no water precautions with young children or infants. Additionally, older children and adults with otorrhea are usually successfully treated with topical antibiotics, whereas younger children and infants are often successfully treated with oral antibiotics. Otorrhea in children under 3 years demonstrates bacteriology similar to that found in AOME (Schneider, 1989). *Pseudomonas, Staphylococcus,* and pathogens frequently found in otorrhea of adults are rare in this age group. The bacteriology of otorrhea in adults more often mirrors the type of pathogens found in external

caal contamination. This suggests that otorrhea in young children is usually caused by the factors responsible for AOME, not by contamination from the external canal (Table 167-2).

A number of investigators have evaluated otorrhea within the first 10 days of tube placement. Herzon (1980) noted a 7.9% incidence of otorrhea in the first 10 days, and Tos et al (1983) found a 12% incidence within the first week. When otorrhea occurs in the immediate postoperative period, it is more likely to be related to the presence of purulent fluid at the time of the surgical procedure than to contamination through the tube or another acute infection. Direct introduction of bacteria into the middle ear via the tube and the unmasking of subclinical infections represent the most probable causes of otorrhea in the immediate postoperative period. Liu et al (1975) found that 52% of ears with serous fluid were culture positive for bacteria and 77% were identified as positive using Gram's stain. Holt and Harner (1980) observed postoperative otorrhea in 67% of children with purulent middle ear fluid, in 54% with mucoid fluid, and in 22% with serous fluid. The incidence of otorrhea in serous fluid is not as high as might have been anticipated from the culture and Gram's stain results of Liu et al and most likely represents effective local defense mechanisms in the middle ears of those patients.

Gates et al (1986) indicated that disinfecting the ear canal could lower the rate of postoperative otorrhea. Baldwin and Aland (1990), using the other ear as a control, cleaned the external ear canal with povidone-iodine before tube placement and found no difference in postoperative otorrhea between the two ears. They did, however, find a higher incidence of postoperative otorrhea in patients with mucoid or purulent middle ear effusions.

A small subset of children, between 2% and 5%, have been identified by a number of investigators to have persistent otorrhea once tubes are placed; the otorrhea persists despite the usual measures to eliminate it. In unpublished work, we have found that some of these children represent one facet of the immotile cilia syndrome. This diagnosis has been established by the demonstration of abnormal cilia on nasal mucosal biopsies.

On the basis of these observations, certain measures seem appropriate to try to decrease the incidence of postoperative otorrhea. If purulent or mucoid fluid is suctioned from the middle ear, topical antibiotics for 3 to 5 days are appropriate. When there is significant bleeding, drops may also help to prevent occlusion of the lumen with coagulated blood.

Myringosclerosis

Tympanosclerosis refers to scar tissue developing in the middle ear but frequently is used to refer to scarring of the tympanic membrane; a more appropriate term for the latter is myringosclerosis. Myringosclerosis is a complication in both treated and untreated OME patients, but it is found more frequently in children who have had tubes (Brown et al, 1978; Kilby et al, 1972; Mackinnon, 1971; Tos et al, 1983). It may be secondary to inflammation (Tos et al, 1979) or to the tube itself (Harell and Shea, 1978). Pichichero et al (1989) found myringosclerosis occurring in 52% of intubated ears compared to a 6% rate in medically treated ears. This finding has been confirmed by Bernard et al (1991) who performed a prospective trial between medical and surgical therapy for COME. They found that the incidence of myringosclerosis was higher (p < 0.01) in the group with tympanostomy tubes (28%) when compared with the medically treated group (6%). In patients with bilateral OME,

Kilby et al (1972) and Tos et al (1983) performed a myringotomy in one ear; in the other ear they performed a myringotomy and inserted a tube. The incidence of myringosclerosis in the nonintubated ear was 19% and in the intubated ear was 48%. From this and other data, they concluded that approximately 10% of patients with OME develop myringosclerosis regardless of treatment, an incidence primarily caused by the severity of the disease. Frequency of intubation neither increased the incidence of myringosclerosis, nor necessarily resulted in scarring in areas closely associated with the tube. Scarring is frequent in both the anteroinferior and posteroinferior quadrants; therefore the tube itself is not likely to be the sole cause of myringosclerosis. The severity of myringosclerosis does not depend on the fluid type.

Most investigators thins scarring represents the end stage of the inflammatory process. With the acute onset of inflammation, the fibrocytes invade the lamina propria, decompose, and hyalinize. The hyalinized debris calcifies and forms the characteristic myringsclerotic plaque. Moller (1981a) showed greater destruction of the more medial circular fibers than of the lateral radial fibers and described a 37% incidence of spontaneous regression of myringosclerosis (Moller, 1981b). The incidence of myringosclerosis was highest in children 11 to 14 years old and lower in older children, providing support for the resolution concept.

No credible explanations for intubation increasing myringosclerosis exist. Foreign body reaction alone could not cause scarring in areas not adjacent to the tube. Tos et al (1983) suggested that the scars form because intubation inhibits tympanic membrane movement and fibrocytes accumulate within the fibrous structure. These fibrocytes then die and form calcified plaques within the tympanic membrane. Whatever the cause, even rather severe myringosclerosis has little effect on hearing. Some studies consider myringosclerosis as a complication of tympanostomy tubes. Since the physiologic and auditory significance of myringosclerosis is negligible, the complication is often considered as cosmetic only.

Persistent perforations

Persistent perforations can occur with any type of tube but have a higher incidence with longer-acting tubes. Perforations occur in less than 5% of the cases that have shorter-acting tubes. The highest incidence of perforation - 25% (Toynbee, 1868) - occurs with the Per-Lee tube. Perforation rates seem to increase as the tube intubation life increases; tubes that stay in longer have higher perforation rates.

Cholesteatoma

The incidence of cholesteatoma associated with ventilation tubes appears to be relatively low. Hughes et al (1974), Holt and Harner (1980), and Brown et al (1978) reported that it occurs in less than 1% of cases; Gunderson and Tonning (1976) reported a 7% rate. The reason for their high incidence of cholesteatoma is unexplained.

Other complications

Direct trauma to the ossicular chain can result in permanent conductive or sensorineural hearing loss; the tympanic segment of the facial nerve is also vulnerable to direct trauma. With adequate anesthesia and canal size for visualization and manipulation,

these complications should not occur. Pichichero et al (1989) retrospectively evaluated children with severe otitis media to determine anatomic and audiologic sequelae of surgical or medical therapy. Those children treated surgically (tympanostomy tubes) had a higher rate of myringosclerosis, tympanic membrane atrophy, and hearing loss than those treated with medical therapy alone. Although this was a retrospective study, the findings demonstrate that intubation of the ear with a tympanostomy tube is not a benign procedure and should be approached with proper surgical skill, caution, and indications.