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Self-Retaining Harpoon Tympanostomy Tube with Applicator

ABSTRACT

Objective: To describe a novel harpoon design for a low cost, self retaining tympanostomy tube with applicator used in a 38-year-old female for otitis media with effusion.

Methods:

- a. Study design: Instrumental Innovation/Case Report
- b. Setting: Tertiary Hospital in Metro Manila

Results: The tympanostomy tube was inserted under endoscopic guidance within 10 seconds, remained in place for two months with relief of symptoms, and spontaneously extruded by the seventh month of follow-up.

Conclusion: The harpoon-designed tube with applicator provided ease of insertion and good anchorage in the tympanic membrane. Maximizing the use of a stylet-needle as both perforator and applicator simplified the tympanostomy and ventilating tube insertion procedures into a single maneuver.

Key words: *middle ear ventilation, tympanostomy tube insertion, grommet insertion, instrumentation*

THE PATHOGENESIS and natural history of middle ear disease were most strikingly altered with the reintroduction of practical, safe and effective middle ear pressure equalization tube (PET) by Armstrong in 1954¹. Otitis Media with effusion (OME) is a common sequel of acute otitis media (AOM). Otagia, aural fullness and hearing loss are the common complaints.

Oral antibiotics remain the treatment of choice for acute otitis media. Over 90% of patients are clinically cured two weeks after the onset of therapy^{2,3}. Acute symptomatic failures are observed, in part due to antibiotic resistance, increasing tympanocentesis recommendations for culture purposes in AOM⁴. For persistent effusion, the most commonly used treatment option for most patients is tube insertion⁵. Myringotomy without tube insertion is not commonly recommended because of rapid closure of the tympanic membrane fenestration⁴. Myringotomy with placement of ventilating tubes has become the standard of care for children with OME that has lasted more than three to four months and is unresponsive to conservative treatment⁶. Tympanostomy tubes are highly effective for children and adults with middle ear effusion, with most remaining free of middle ear disease while the tubes remain patent and functional⁷. Prolonged middle ear ventilation of approximately 6 to 12 months provided by most first line PETs helps to restore the Eustachian tube- middle ear-mastoid complex to a more normal physiologic state, improving hearing and preventing infection⁸.

Because of prohibitive costs and inavailability of commercial tympanostomy tubes, it is common practice in our institution to fabricate myringotomy tubes from 18-gauge intravenous plastic catheters cut into 5 mm segments and heat-flanged over both ends. We describe a novel low-cost, self retaining harpoon tube with applicator that facilitates both tympanostomy and insertion into, as well as anchorage and retention in, the tympanic membrane.

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Table 1. Tympanostomy Tubes Manufactured by MedtronicXomed, USA locally distributed by FAMED Company

Type	Price per box(5pcs)	Price per piece
Sheehy Collar Button	Php 5,610	Php 1,122
Shepard Grommet	Php 3,300	Php 660
Pediatric	Php 3,630	Php 726
Goode T-tube	Php 6,930	Php 1,386

To compute for the total cost in the production of one set of the device, the cost of one piece of IV catheter, one piece of tuberculin syringe and ¼ of the total amount in the fabrication of the tube were added giving a sum of Php57.25.

Procedure:

A. Tympanostomy Tube Fabrication

A 2 x 1cm. piece of aluminum foil was rolled around the intravenous plastic catheter about 1 mm from its tip to serve as guide, with the stylet needle used as stopper. The rim edge was smoothed with a sharp blade (Figures 1 & 2). The rolled aluminum foil was slid further away to 2 mm from the catheter tip, and two slits 180° apart were cut into both sides of the catheter, each starting from the edge of the guide aluminum foil and extending 1 mm towards the tip. The stylet prevented each cut from extending to the other side of the catheter (Figure 3). The flaps made on each proximal side of the catheter were then elevated and folded, and the distal side of the catheter was cut 5-7 mm from the tip, and the rim was flared over an open flame.

Alternately, two tongue depressors could be used as template, cutting a groove in both tongue depressors for the catheter to fit between them when placed together, exposing 2-3 mm of the tip to be flared. It could then be secured with a clip and heated over an open flame (Figure 4). The procedure was repeated to fashion four tubes (Figure 5).

B. Tympanostomy Tube Applicator Set:

A second 18 Gauge intravenous plastic catheter was marked alongside the fabricated tympanostomy tube and cut at a point from the tip corresponding to the tube length. The stylet was reinserted into the intravenous catheter, and the cut portion of the intravenous catheter and fabricated tympanostomy tube were reinserted into the stylet (Figure 6). After trimming excess portions of the intravenous catheter that could interfere with insertion (Figure 7), the assembly was attached to a tuberculin syringe to serve as handle (Figure 8) and soaked for 30 minutes in Glutharaldehyde 2% (Glutharex™ 3M, Columbia) for sterilization then rinsed with sterile distilled H2O.

Note that the tube's end was modified into a harpoon-like structure which was incorporated into the tip of an intravenous catheter system to become a self-retaining tympanostomy tube with applicator. Using the attached tuberculin syringe as a handle, the metal stylet of the intravenous catheter was designed to puncture the tympanic membrane and facilitate tube insertion in one motion. The arrow-

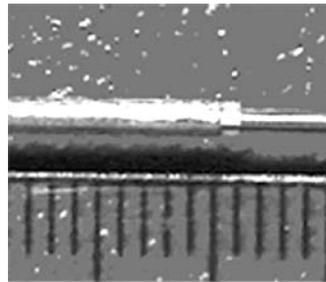


FIGURE 1: Aluminum foil used a guide

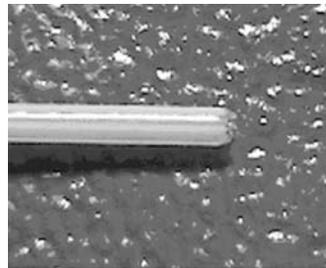


FIGURE 2: Smoothened edge

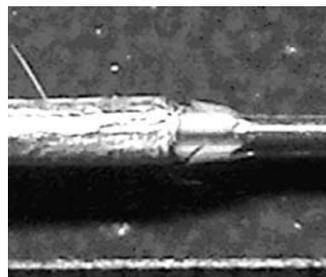


FIGURE 3: Make a slit 180° apart

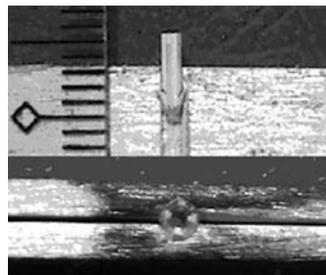


FIGURE 4: Tongue depressors as template in burning one end to make a flare end



FIGURE 5: Finished product of a tympanostomy tube

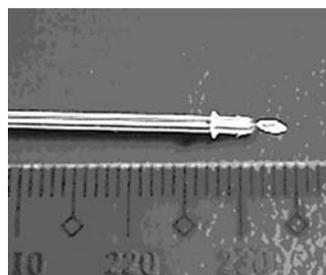


FIGURE 6: Reinsert the new IV catheter and the fabricated tympanostomy tube into the stylet

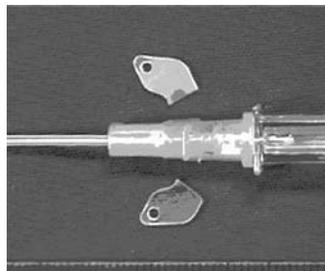


FIGURE 7:
Remove parts that may interfere with VT insertion



FIGURE 8:
Attach the assembly to a tuberculin syringe to serve as handle



FIGURE 9:
Insertion of the tube

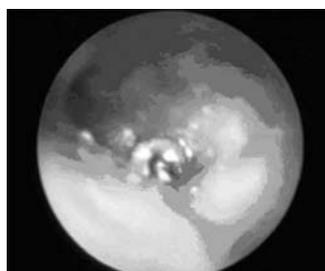


FIGURE 10:
Tympanostomy tube in place

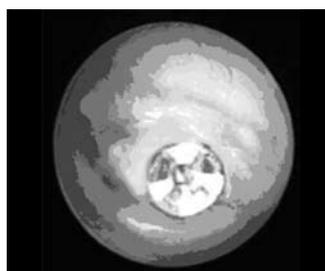


FIGURE 11:
2 months follow-up

head design automatically leaves the tube in place after applicator withdrawal.

RESULTS

With institutional review board approval and informed consent, the device was used on a 38-year-old female with eight months' aural fullness and hearing loss unrelieved by medications diagnosed to have otitis media with effusion. Tympanostomy tube insertion was performed under topical anesthesia using Lidocaine 25 mg, Prilocaine 25 mg, 5% cream (EMLA™ AstraZeneca) applied for 15 minutes. A 2.7 mm O° rigid scope (model 8670.31 Wolf USA) and Telecam video system (SL NTSC, Karl Storz, Germany) were used to document the procedure (Figures 9&10). The tube was applied within 10 seconds, obtaining clear serous fluid with relief of symptoms. The tube was in place at one week and two months follow-up (Figure 11), and spontaneously extruded by the seventh month follow-up.

DISCUSSION

There are many different types of tympanostomy tubes currently in use. They differ in size, shape, materials, coatings and theoretical advantages for the surgeon or patient. Commercially available tympanostomy tubes are expensive and burdensome to our financially constrained patients. The cost of a single tympanostomy tube obtained from local suppliers ranges from Php 500 to Php 1,500 depending on the type & brand (Table 1). The fabrication of this device will only cost Php 57.25.

In our local hospital setting, tympanostomy tubes were improvised using a gauge 18 intravenous catheter. One IV catheter was cut and reduced into four 10 mm long tubes with both ends of the tubes heated to make patent flared rims. The technique of myringotomy and ventilating tube insertion was the same as the standard procedure.

The new self retaining tympanostomy tube with applicator is designed to aid the surgeon in performing myringotomy and ventilating tube insertion in a single maneuver. This instrument was inspired by the principle of inserting a catheter intravenously with the aid of a stylet-needle that is subsequently withdrawn to leave the catheter in place. To keep the new tympanostomy tube in place, it is designed like a harpoon which facilitates smooth insertion but is kept automatically in place upon slight retraction with the aid of the hooks located on each side of the tube (Figures 12-14). The stylet-needle functions as perforator and applicator eliminating the need for a tympanostomy blade further reducing the expense for the procedure. The attached syringe not only serves as a convenient handle but is also very useful in aspirating discharge for specimen collection, hence, making myringotomy and tympanostomy tube insertion less time consuming.

The device can be used under local or general anesthesia. The tympanic membrane can be visualized with or without the use of an aural speculum, under otomicroscopic magnification, or video-endoscopic guidance. During the procedure, care should be given not to injure the external auditory canal or any other part of the tympanic membrane. The plastic IV catheter may be slid gently forward using the middle finger until the posterior flange end touches the tympanic

MATERIALS AND METHODS			
Material	Manufacturer	Amount	Cost (PhP)
INTRAVENOUS CATHETER 18 GAUGE, 1.3 x 45 mm	INTROCAN-W, B.BRAUN Laboratories, Brazil	2	36.50 each
TUBERCULIN (1ml) SYRINGE	Becton, Dickinson & Co. Singapore	1	6.50 each
BLADE No. 11	Feather, Safety Razor Co., LTD, Japan	1	10.00 each
CANDLE	LIWANAG, Sevilla Candle Factory, Malabon City, Philippines	1	7.00 each
TONGUE DEPRESSOR	Union Wooden Tongue Manufacturing Co. Philippines	2	0.50 each
ALUMINUM FOIL	Paramount Foil Manufacturing, U.S.A	2cm x 1cm	negligible

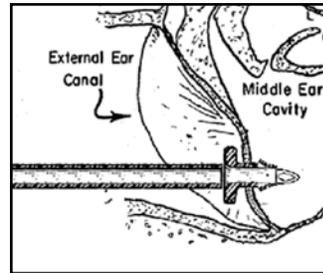


FIGURE 12: Insertion of the device into the external auditory canal

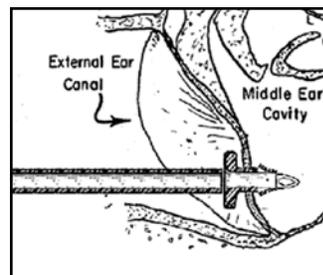


FIGURE 13: Insertion of the device through the tympanic membrane

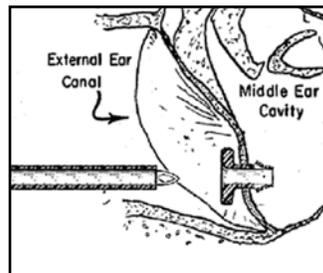


FIGURE 14: Withdrawal of the device leaving the tube in place

membrane. Special attention should be given to introduction of the device, inserting the tube until the hooks have penetrated the tympanic membrane and gently retracted until the hooks are secured. Avoid pushing the device way beyond the tympanic membrane into the middle ear cavity. Such an occurrence is a remote possibility owing to the relatively smaller puncture produced by the needle compared to the larger posterior flange of the device which functions as a stopper, but could potentially happen if extreme force is applied. The device should self-extrude, but removal may be performed with fine serrated end ear microforceps.

This modification in the fabrication of a tympanostomy tube from a gauge 18 IV catheter made tube application fast and easy. The harpoon design facilitated tube insertion into the tympanic membrane and helped keep the tube in place. Aside from the low cost of material in the production, maximizing the use of stylet-needle, functioning as perforator and applicator eliminated the need for a tympanostomy blade, which simplified the tympanostomy and ventilating tube insertion procedures. Although the device was used effectively and safely in one patient, evidence is lacking with regards extrusion rate, risks and complications and further studies of its use on a larger sample size with longer duration of follow-up and comparison with commercially available tympanostomy tubes are suggested.

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