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Ventilation Tubes Versus Conservative Treatment in Management of Secretory Otitis Media in Adenoidectomized Children

SHERIF SHAABAN, M.D.; ASHRAF RAGAB, M.D. and MOHAMED AL AYADI, M.D.

The Department of Otolaryngology, Faculty of Medicine, Cairo University.

Abstract

The study was carried on 79 adenoidectomized patients suffering from secretory otitis media. Forty patients received medical treatment for 3 weeks consisting of decongestant nose drop, septazol suspension, phenadone syrup with one of three different types of mucolytic agents. The cure rate was 53.3%, 40% and 40% according to the mucolytic agent used as a part of the combination therapy. The average cure rate of medical treatment was 45%. In another 39 patients myringotomy and insertion of ventilation tubes were done. The 4 commonly used ventilation tubes were the Shepard Grommets, Collar Button, T tube and Paparella tube in 34, 8 and 4 ears respectively, to compare the incidence to complications including otorrhoea, obstruction and extrusion. The average follow up was 5 months.

Introduction

TYMPANOSTOMY tubes were to serve two primary functions: middle Ear ventilation and pressure equalization.

It was hoped that, through these functions, tympanostomy tubes would prevent the accumulation of middle ear effusion and thereby eliminate its associated conductive hearing loss and recurrent infections.

Subsequent to Armstrong in 1954 publication, controversy has risen regarding the use of tympanostomy tubes, not only between professional disciplines but within the discipline of otology itself.

Paradise [1] warned that tympanostomy tubes insertion was not without hazard and should be utilized only when condition being treated was troublesome enough to warrant a surgical procedure and only when equally effective but less risky alternatives were not available.

Obviously, when considering any therapeutic modality, potential benefits must be weighed against potential determents.

Mucolytic therapy in secretory otitis media is based on the hypothesis that treatment of thick, tenacious secretions with mucolytic may decade its structure sufficiently to produce a decrease in viscosity, elasticity and clearness of secretions that block the Eustachian tube.

Material and Methods

The study included 88 adenoidectomised patients seen at the outpatient E.N.T. clinic of Kasr El Aini Hospital, Cairo University. Seventy nine patients continued in the study and 9 patients were lost during follow up. Their ages ranged between 3 and 15 years and the median age was 6.67 years. The sex distribution was 38 males and 41 females.

Patients were suffering from deafness, irritation in the ear and/or recurrent attacks of acute otitis media. They were diagnosed as chronic secretory otitis media. None of them had cleft palate or history of allergy.

All patients were subjected to the following studies.

- Careful History taking.
- Full E.N.T. examination.
- Tympanometry and acoustic reflex measurement using Amplaid 702 impedance bridge. Secretory otitis media was diagnosed on the the basis of otological examination coupled with tympanometric results of either a type B flat or C2 curve with negative pressure of less that -250 mm H_2O. Patients were randomized into 2 groups.

Group I: Comprises 40 patients, all received a course of conservative therapy for three weeks in the form of otrivine 0.5% nasal drops (1-2 drops tds), phenadone syrup (children below 6 years received 1/2 teaspoonful tds while children above 6 years received one teaspoonful tds), septazol suspension (children below 6 years received one teaspoonful daily while children above 6 years received two teaspoonful twice daily) and a mucolytic agent.

For 15 cases Bisolvon elixir syrup (Bromhexine hydrochloride) was used as a mucolytic (children below 6 years 1/2 teaspoonful tds while children above 6 years one teaspoonful tds). For a second group of 15 cases mucolase syrup (S-Carboxymethyl optema) was used as a mucolytic (children below 5 years received 1/2 teaspoonful tds while children above 6 years received one teaspoonful tds). For the third group of 10 cases chymotrypsin injection was used (18 μ/kg by IM injection once daily). At the end of the third week of conservative therapy otoscopic examination, tympanometry and acoustic reflex measurement were done to evaluate the effect of combination therapy.

Group II: 39 patients treated surgically with myringotomy and insertion of different types of ventilation tubes. The indications for insertion of ventilation tubes were as follows:

1- Otitis media with effusion with no evidence of inflammation, flat tympanogram and bilateral conductive hearing loss for at least three months period.

2- Otitis media with effusion, recurrent suppurative otitis media greater than or equal to 4 episodes in the previous 12 months period.

3- Failure of conservative therapy.

Ventilation tubes used were:

1- Shepard grommets with an internal diameter of 1.14 mm. (17 pts).

2- Collar button tubes with an internal diameter of 1.27 mm. (16 pts).

3- Goods Tube with an internal diameter of 1.32 mm. and average length of 4.78 mm. (4 pts).

4- Paperella medium sized tubes with an internal diameter of 1.27 mm. (2 pts).

All tubes were placed under general anesthesia using the Zeiss operating Microscope.

Follow up and observation:

Each evaluation consisted of an interval history, an ear nose and throat examination including tympanometry, acoustic reflex and tuning fork tests if possible.

During the tubulation period the patients were seen every month and any complications appeared were managed accordingly e.g. for otorrhoea we used repeated aspiration and application of antibiotic corticosteroid drops with systemic antibiotics.

The follow up rate was 89.8% and was continued for five months.

Results

The clinical examination and tympanograms of ears after 5 months period, showed that for group I, composed of 40 patients who received conservative therapy and different types of mucolytics, 18 cases improved out of 40 cases and so the overall cure rate is 45%.

- 8 cases (20%) received Mucolase as mucolytic agent,
- 6 cases (15%) received Bisolvon as a mucolytic agent and
- 4 cases (10%) received α chemotrypsin as proteolytic agent.

Out of 40 patients receiving conservative therapy, (group I) 13 patients had a history of at least one pervious grommet tube insertion.

In cases of group II (39 patients treated surgically myringotomy and insertion of different types of ventilation tubes) the results were as follows:

Subgroup A:

For 17 pt (34 ears) myringotomy and insertion of Shepard grommet was done. At the end of the fifth month the following data were obtained:

The incidence of otorrhoea was	23.5%	(8 ears)
The incidence of obstruction was	26.5%	(9 ears)
The incidence of extrusion was	23.5%	(8 ears)
The still functioning tubes were	17 tubes	(50.0%)

Subgroup B:

For 16 patients (32 ears) myringotomy and insertion of Collar Button tubes was done. At the end of the fifth month the following data were obtained:

The incidence of otorrhoea was	31.2%	(10 ears)
The incidence of obstruction was	12.5%	(4 ears)
The incidence of extrusion was	12.5%	(4 ears)
The still functioning tubes were	24 ears	(75%)

There is a significant difference between the Shepard grommets tubes and the Collar Button tubes in the persistence of patency (still functioning) at the end of the fifth month of insertion, where 75% of

Collar Button tubes were still functioning in comparison with 50% of Shepard grommet ($p < 0.05$).

Subgroup C:

For 4 patients (8 ears) myringotomy and insertion of T tubes was done. At the end of the fifth month otorrhea occurred in 3 ears and was relieved by medical treatment, no obstruction or extrusion was detected during this period.

Subgroup D:

For 2 patients (4 ears) myringotomy and insertion of medium sized Paparella tubes were done. Otorrhoea occurred in 2 ears and was relieved by medical treatment, no obstruction or extrusion detected.

No significant difference in the incidence of otorrhoea between T tube and Paparella tube.

Type of effusion:

- 27 ears our of 78 ear (92.3%) proved fluid in the middle ear
- 64 ears (88.9%) contained mucoid effusion.
- 8 ears (11.1%) contained serous effusion.

Table (1): The Results of Conservative Therapy Using Different Types of Mucolytic. (Significance = 0.7141).

	Improved		Unimproved		Total	
	No.	%	No.	%	No.	%
Subgroup 1 (Mucolase)	8	53.3	7	46.7	15	37.5%
Subgroup 2 (Bisolvon)	6	40	9	60	15	37.5%
Subgroup 3 (Chemotrypsin)	4	40	6	60	10	25%
Total	18	45%	22	55%	40	100%

Table (2): The Results of Conservative Therapy for Patients with Previous Grommets Insertion in Relation to other Patients with No History of Previous Grommets Insertion. No Significant Difference was Found between both Groups.

	Improved		Unimproved		Total	
	No.	%	No.	%	No.	%
No previous surgery	13	48.1	14	51.9	27	67.5
Previous surgery	5	61.5	8	38.5	13	32.5

Discussion

The results of treatment of 40 patients with secretory otitis media, with different combination therapy (group I) show that 18 patients improved (45%); of them 8 cases (20%) received Mucolase as a mucolytic agent, 6 cases (15%) received Bisolvon as a mucolytic agent and 4 cases (10%) received chymotrypsin as a proteolytic agent.

The small difference, between Mucolase, Bisolvon and Chymotrpsin, observed in this trial is of no statistical significance.

Taylor and Dareshani [2] studied the effect of carbocystein in glue ear. They found that at the end of one month of treatment 30.4% had an excellent result, whereas with placebo this figure was 2.2%.

Ramsden et al. [3] failed to demonstrate a significant reduction in the eventual requirement for surgery in children treated with carbocysteine.

Khan et al. [4] studied carbocystein and decongestant antihistaminic and found that carbocystein was significantly better in speeding resolution of the effusion after surgery. Khan [4] supports the view that carbocystein is a beneficial adjuvent in the resolution of middle ear effusion in secretory otitis media children.

Hughes [5] used carbocystein and Actifed separately and in combination in the management of secretory otitis media and found no statistically significant benefit in avoiding the need for surgical treatment, but carbocystein was statistically more successful in bringing about resolution in the post operative period.

In this study a higher incidence of improvement occurred with carbocysteine (mucolase) than Bisolvon or chemotrypsin, however,this difference was insignificant, but may become significant with larger samples and remains a matter for further extensive trials.

Wing [6] reported that a combination of Bisolvon and Actified gave 90% success in an open study in patients with secretory otitis media.

Although there are no reports of mucolytic-antibiotic combinations used in the treatment of secretory otitis media, those studies carried out in lung disease suggest that the combination would be beneficial not only in increasing the level of antibiotic but also in improving mucociliary clearance.

Stenfors and Raisanen [1] found that antibiotic treatment in secretory otitis media could have theoretical successes rate around 30%.

Healy [8] found that after 4 weeks of treatment with co-trimoxazol 66% of the middle ears had become air filled, in contrast to 19% in the untreated group.

In this study 45% improved by impedance measurement and otoscopically with septazol in combination therapy.

As regards to the use of corticosteroids in the treatment of secretory otitis media Oppenheimer [9] found that children over 8 years old were more likely to respond to corticosteroids.

Prisco et al. [10] reported on 276 children with otitis media of all types, of 160 children treated with prednisolone 53% achieved complete tympanometric and otoscopic resolution compared with 13% of 116 children responded when just treated with ampicillin.

In this study, the use of phenadone syr-

up with a combination therapy for treatment of secretory otitis media resulted in 45% improvement of cases both otoscopically and by impedance measurements.

Surgical treatment of otitis media with effusion includes adenoidectomy, paracentesis and insertion of ventilation tubes.

In the present study we found that most cases of glue ear seem to be controlled by the insertion of grommets on one occasion. A proportion of children will continue to have problems after extrusion of the grommets necessitating repeated procedures.

Although there have been numerous modifications in tube shape, composition and alteration of insertion techniques over the past 30 years, there is a little information in the literature to aid the otolaryngologist in the selection of the appropriate tympanostomy tubes.

In this study 4 common tympanostomy tubes, Shepard Grommets, Collar Button tube, T tube and Paparella tube, were used to determine which of these tubes had the fewest number of post placement complications, including otorrhoea, tube obstruction and extrusion in the follow up period of 5 months. Children included in this study had their adenoids removed to exclude its effect on the results.

Othorrhoea is the most commonly described complication of tube placement. Gates et al. [11] showed variation from 15 to 74% of the incidence of otorrhoea.

In this study the incidence of otorrhoea for Shepard Grommets was 23.5% and that for Collar Button tube was 31.2% while 3 out of 8 ears with T tube showed otorrhoea, 2 out of 4 ears with Paparella tube showed otorrhoea. The over all incidence of otorrhoea in this study was 29%. No significant difference between different types of tubes has been realized as regards to the occurrence of otorrhoea.

Gates [12] found that the incidence of otorrhoea was 24% for Shepard Grommets without adenoidectomy, while Weight et al. [31] reported that 42% of children showed otorrhoea during the presence of grommets tube Weigel et al. [19] reported incidence of otorrhoea with T tube as 50%.

So the incidence of otorrhoea for Shepard Grommets (23.5%) seems to be in the mid-region of the range quoted in literature.

Luxford and Sheehy [14] reported that the incidence of otorrhoea of Collar Button tubes was 19% during the follow up of 6 months, while Balkany et al. [15] reported that otorrhoea occurred in 17% of cases with Collar Button tubes in 6 months period and Barford and Resborg [16] reported 34% incidence of otorrhoea which is nearer to the incidence of otorrhoea in this study (31.2%).

Rothera and Grant [17] found that otorrhoea occurred in 20% of cases with T tube. Gates [12] reported that 50% of cases with T tube showed otorrhoea in a period of 2 years. Von Schoenberg et al. [21] reported 70.4% incidence of otorrhoea for T tube in a period of 1.5 years.

Stack et al. [18] reported that the over all incidence of otorrhoea was 20.6% with markedly higher incidence of 40% with Paparella tube and 6% with Shepard Grommet.

In the present study Obstruction of the tube, either temporary or permanent, occurred in 26.5% of cases with Shepard Grommets and in 12.5% of cases with collar Button and no cases reported in cases of

T tube or Paparella tube during the following up period of 5 months.

Weight et al. [19] reported that obstruction occurred in 11% of cases with Shepard Grommets and 36% in cases with T tubes.

Obstruction occurred for a number of reasons, tube length, tube inner diameter, tube composition and period of intubation.

Extrusion of the tube occurs because it acts as foreign body interrupting the normal migratory stream of epithelium.

Spontaneous extrusion occurred in 23.5% of cases with Shepard Grommets, 12.5% of cases with Collar Button tubes and no cases of extrusion for cases with T tube and Paparella tube. This may be due to the relatively short period of follow up as they are considered term ventilation tubes.

So, 50% of Shepard Grommets were still functioning at the end of 5 months period, while the other 50% were either blocker or extruded and 75% of Collar Button tubes were still functioning.

There is a significant difference between Shepard Grommets and Collar Button tubes as regards the still functioning tubes at the end of 5 months, with $p < 0.05$.

All T. tubes and paperella tubes were still functioning at the end of this period.

Bingham and Millory [20] reported that 50% of Shepard Grommets extruded by 6 months and 100% extruded by 15 months.

Shone and Griffith [21] reported that 52% of Shepard Grommets were still functioning at 6 months and 25% and 4% were still functioning at 8 and 12 months respectively.

Weiget et al. [19] reported 30%, 50% and 94% of Shepard Grommets extruded by 6, 12 and 24 months respectively while for T tube 10%, 19% and 31% extruded by 6, 12 and 24 months and residual perforation occurred in 12% of T tubes after extrusion.

Von Schoenberg et al. [22] reported 44.9% extrusion rate of T tube at 30 months of insertion and 47.5% showed residual perforation after extrusion of T tubes.

Luxford and Sheehy [14] reported 80% of Collar Button tubes were still functioning at 6 months period and most of them extruded within 9-18 months.

The results in this study are similar with that of Luxford and Sheehy [14] Shone and Griffith [23] and Gates et al. [11].

So from the aforementioned data we can conclude that in adenoidectomized patients we recommend to start with medical treatment of combination therapy consisting of local decongestant drops (Otrivine), systemic steriod (Phenadone Syrup), antibiotic (Septazol suspension) and a mucolytic agent (Mucolase, Bisolvon or chemotrypsine) for a period of 3 weeks. If after 3 weeks, conservative treatment failed, the surgical treatment is indicated.

The proper choice of ventilation tube has been a perplexing problem for clinical otolaryngologists and the ideal tube certainly has not been found.

This study showed a higher incidence of still functioning Collar Button tubes than that of Shepard grommets (75% versus 50%) with a significant difference between them ($p<0.05$) at the end of 5 months, so Collar Button tubes could be

more efficious for use in pediatric population of recurrent acute otitis media or chronic otitis media with effusion.

T tubes should be reserved where long term of ventilation or permanent middle ear ventilation is warranted.

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