Academia Journal of Medicinal Plants 8(6): 000-000, June 2020
DOI: 10.15413/ajmp.2020.0117
ISSN: 2315-7720

Academia Publishing

Research Paper

Evaluation of different diagnostic tools for post-surgical balloon dilation Eustachain tuboplasticy: A clinical study

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Accepted 8th June, 2020

ABSTRACT

The present study was conducted to assess the sensitivity of routine tools for post-surgical effect evaluation of balloon dilation Eustachian tuboplasticity. A total of 34 patients diagnosed with chronic secretory otitis media underwent uni- or bilateral dilation Eustachian tuboplasticity between Jan 2016 to Jan 2018. Routine physical examinations, R value of the tubomanometry, acoustic impedance, Eustachian tube score and Eustachian tube dysfunction -7 questionnaire was used to evaluate pre- and postoperative tube function. All patients underwent follow-up with post-operative intervals at 2 weeks, 1-month and 3 months after surgery. Among all the routine tools evaluated, Eustachian tube score and R values showed the quickest change. Eustachian tube dysfunction -7 questionnaire and acoustic impedance showed improvements after 1-month post-surgery. Dilation Eustachian tuboplasticity is a minimally invasive and effective treatment for chronic secretory otitis media. Eustachian tube score was the most sensitive measure to evaluate patients' symptoms after surgery. However, we do not recommend it be used as the only instrument for effective evaluation after dilation Eustachian tuboplasticity due its variability between different investigators and different times of investigation.

Key words: Balloon dilator, Eustachian tube, Ear diseases , otitis media.

Abbreviation: ETS, Eustachian tube score; **ETDQ-7,** Eustachian tube dysfunction -7 questionnaire; **ETD,** Eustachian tube dysfunction; **BET,** balloon dilation Eustachian tuboplasticy; **CSOM,** secretory otitis media; **TM,** tympanic membrane.

INTRODUCTION

Eustachian tube (ET) which connects the middle ear spaces with the nasopharynx is responsible for pressure equilibration and sound transmission (Schroder et al., 2015a). Obstruction of the ET is a common disorder due to its narrow canal. This leads to a variety of clinical symptoms such as ear obstruction, fluctuating hearing loss and bubble sounds in the ear. There are several reasons for Eustachian tube dysfunction (ETD), that is, virus infection, allergy, dysplasia, laryngopharyngeal reflux, and dysfunction of cartilage dilation, to name a few (Ockermann, 2010). Balloon dilation techniques are widely used to treat ETD. This technique combines an endoscope with a balloon catheter to help dilate the narrow canal, whether it is in the cartilaginous portion or the cartilaginous and bony portion (Poe, 2011). A number of methods have been used to estimate the pressure equalizing function of the ET. These include a pneumatic otoscopy to assess tympanic membrane (TM) position and mobility, or performing a Valsalva maneuver, Politzer's test, ET catheterization, Toynbee test, tympanometry, the Holmquist test, Bluestone's nine step test, sonotubometry or manometry. However, there is no gold standard for the objective measurement of ET function and effect evaluation after balloon dilation Eustachian tuboplasticy (BET). Because of the high prevalence of subjective patient complaints, we tried to identify a tool that combines both subjective and

Table 1: Eustachian tube score.

Symptoms	2 Points	1 Point	0 Points
Clicking noise by swallowing	Always	Infrequent	No clicking
Clicking noise by Valsalva	Always	Infrequent	No clicking
TMM 30 mbar	R < 1	R ≥ 1	No P
TMM 40 mbar	R < 1	R ≥ 1	No P
TMM 50 mbar	R < 1	R ≥ 1	No P

TMM = tubomanometry; P = opening of Eustachian tube.

objective elements for evaluation. ETS was introduced in 2010 to study outcomes of BET (Ockermann, 2010). It was proven to be a valid and reliable instrument to diagnose adult patients with chronic obstructive ETD (Schroder et al., 2015). However, there is concern regarding the lack of evidence to support the sensitivity or validity of Eustachian tube score (ETS) for evaluating the effect of BET. In this study, we evaluated the effectiveness and safety of using balloons for dilation of the cartilaginous ET in patients with chronic OME. In addition, we evaluated ETS and Eustachian tube dysfunction -7 questionnaire (ETDQ-7) of patients subjective complains to determine whether ETS was a suitable index to assess the effect of BET.

MATERIALS AND METHODS

This study was conducted from Jan 2016 to Jan 2018. A total of 34 patients with chronic secretory otitis media (CSOM) were enrolled. Patients were between 21-60 years old, with a mean age of 37.6±13.2 years. All patients were diagnosed with CSOM based on the clinical guidelines of the 2016 AAO-HSN of secretory otitis media. Enrolled patients had routine examinations of the tympanic membrane, middle ear, nasal cavity and nasopharynx. Abnormal impedance audiometry was used as criteria to verify diagnosis at the time of enrollment. Patient exclusion criteria were as follows: surgery of the head or neck within the last 3 months; a history of radiation therapy to the head and neck; sinonasal malignancy; evidence of acute infection; nasal polyposis; congenital malformations such as cleft palate and craniofacial syndrome; or other systemic disorders. All patients had been treated with auto insufflation, topical decongestant, antihistamine and nasal steroids for at least 3 months prior to enrollment and had no response to conservative management. We performed eustachain tube balloon dilation in these patients. Follow-up examinations were scheduled for 1 and 3 months postoperatively. We evaluated the effect of balloon dilation by comparing tubomanometry and Eustachian tube dysfunction questionnaire (ETDQ-7) results before and after surgery.

Institutional ethics approval was obtained from Zhuji Affiliated Hospital ethics committee. All patients who enrolled in the study were provided with approved patient information sheets and signed informed consent forms.

ETDQ-7 questionnaire

We used the ETDQ-7 questionnaire which was first developed by McCoul et al. (2012). The questionnaire gathers patient information for aural fullness or pressure, sensation of clogged or muffled hearing, recurrent or persistent middle ear effusion etc (Table 1).

Tubomanometry and R value measurement

To measure the R value, we used a Tubomanometry (Eustachian Tube Diagnostic Tubomanometer, La Diffusion Technique Francaise, SaintEtienne, France) in this study (Figure 1A). The procedure was as follows: one airtight manner was connected to the nasal vestibule allowing discharge of high pressure due to the closure of the velum when swallowing, two pressure transducers measured the pressure in the nose and nasopharynx and the external ear canal respectively. Subjects were instructed not to swallow during the tympanometry–tympanometry test cycle. An electronic processor was used to analyze the signals provided by the pressure transducers when pressure increased (Figure 1B, C). A computer connected to the tubomanometer recorded the pressure graphs over time for both the nasopharynx and external ear canal. MEP was calculated based on the pressure changes. A change in the MEP was considered a confirmation of the successful opening of the ET. A threshold MEP change of 5 or 10 daPa was set as a valid ET dilation. The tubomanometry test was performed at 30, 40 and 50 mbar. Whenever the ET opening resulted in an MEP change, the patient was requested to swallow multiple times to equalize the MEP and return the TM to the initial neutral position before the next test was performed.

In the present study, TMM had to initially demonstrate a recordable tube opening. If tube opening was registered, the time of opening in relation to the pressure applied was measured. The TMM calculates the opening latency index or index R. An R value of ≤1 indicates early opening of the tube

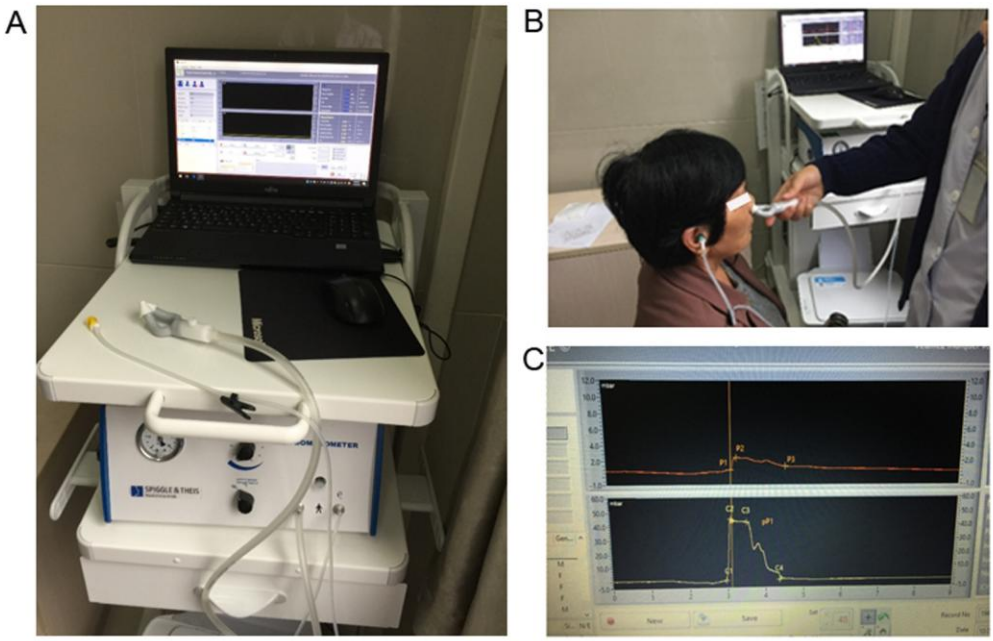

Figure 1: Device and method to measure R value. A) Tubomanometry; B) Tubomanometry performed by a technician; C) Pressure curves of the epipharynx and ear canal.

Table 2: The seven-item Eustachian tube dysfunction questionnaire.

Over the past 1 month, how much has each of the following been a problem for you?	**No Problem**				**Moderate Problem**		**Severe Problem**
1. Pressure in the ears?	1	2	3	4	5	6	7
2. Pain in the ears?	1	2	3	4	5	6	7
3. A feeling that your ears are clogged or "under water"?	1	2	3	4	5	6	7
4. Ear symptoms when you have a cold or sinusitis?	1	2	3	4	5	6	7
5. Crackling or popping sounds in the ears?	1	2	3	4	5	6	7
6. Ringing in the ears?	1	2	3	4	5	6	7
7. A feeling that your hearing is muffled?	1	2	3	4	5	6	7

at the start of application of the stimulus, and was considered optimal. A value >1 indicates late opening of the tube after the initial stimulus and is interpreted as suboptimal. Inability to calculate the index R value indicates that the tube is unable to actively open. All TMM results were encoded for the evaluation. An $R \leq 1$ was encoded with two points, an $R > 1$ with 1 point and no R-value with 0 points for the measurements at 30, 40, and 50 mbar, respectively.

ETS

The ETS consists of three tubomanometric measurements and two subjective estimations of the patients Valsalva's and Toynbee's clinical symptoms (Table 2). Based on the definition proposed by Ockermann et el. (2015), positive Toynbee's clicking sound when swallowing and positive Valsalva's maneuver were rated with 0 points for "never," 1 point for "sometimes," and 2 points for "always".

Eustachian tube balloon dilation

Eustachian tube dilation was performed under general anesthesia. The nose was first decongested using 1% epinephrine gauze. A balloon catheter (Spiggle & Theis, Germany, Figure 2A) was then inserted into the Eustachian tube under a 0° nasal sinus endoscopic control length of 2 cm (preset by the manufacturer) and then fixed. After the balloon was positioned correctly, it was inflated using saline solution for 2 min at a pressure of 10 bar (Figure 2B). All patients were administered oral antibiotics for 3 days after the procedure.

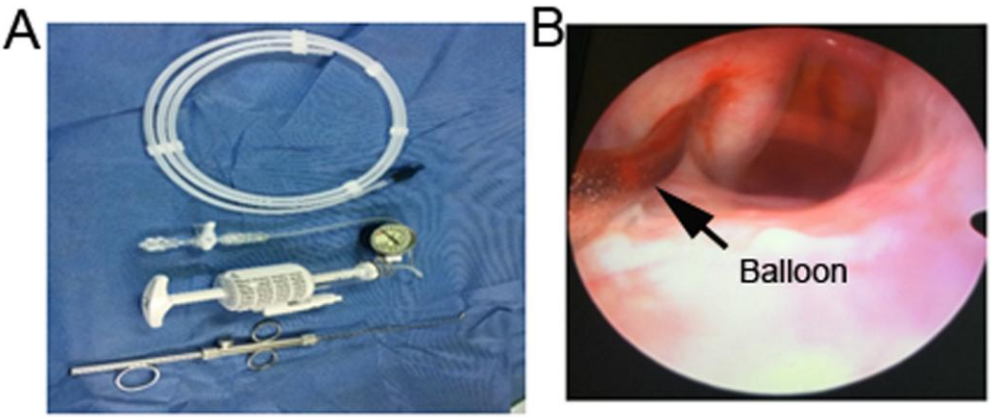

Figure 2: Instruments and endoscopic procedure of BET. A Instruments used to perform BET. B The arrow indicates the position of the balloon in the right Eustachian tube.

Statistical analysis

Data from patients were analyzed as a self-control experiment, and comparisons were made before and after treatment. Statistical analysis was performed using SPSS for Windows (SPSS, Inc, Chicago, Illinois, USA). McNemar test with matched pairs of cases was performed using a $p < 0.05$ as the significance limit for effusion, tympanometry, and Valsalva maneuver results. The Scheffé statistic test was performed to compare ETS between pretreatment and follow-up visits.

RESULTS

BET was performed as a unilateral or bilateral procedure for 34 adult patients (20 males, 14 females) who had symptoms of chronic obstructive ET dysfunction. Two patients had bilateral and 32 patients had unilateral ET dysfunction.

The placement of the catheter via the guiding endoscope was successful for all 34 patients. We initially placed the catheter adjacent to the ostium, and then the balloon catheter was pushed forward until resistance was felt. No obvious complications, such as bony fracture, or balloon failure during the procedure were encountered. One patient had post-nostril bleeding one day after the procedure.

Post operation evaluation using ETDQ-7

Postoperative follow-up examinations were performed at 2 weeks, 1 and 3 months after BET. Improved ETDQ-7 scores were observed for all cases after the 1st month post-procedure. The mean ETDQ-7 score before the procedure was 35.89 ±5.4 and was 34.47±5.25 at the second week post-operation. Statistical analysis showed no improvement. At the one-month and 3-month follow-up, ETDQ-7 decreased to 26.03 ±5.58, and 14.85±6.32, respectively. The feeling of clogged ear and muffled hearing improved dramatically. Prior to the operation, all patients had symptoms of aural fullness and ear muffling. Subjective postoperative improvement was defined as the change in severity for at least 3 symptoms, that is, sever to moderate for symptoms of ear pressure, click sound in ear and ear muffling. Twenty-seven patients (87.1%) showed improvement at the one-month follow-up, and 30 (96.8%) patients showed improvement at the 3-month follow-up. One patient showed no improvement at the 3-month follow-up period (Figure 3A). We followed-up this patient for an additional 3 months, after which tympanotomy tube insertion was performed.

Post operation evaluation by eustachian tube score (ETS)

TMM was used to objectively determine the function of ET. ETS showed improvement for all cases in post operation follow-up examinations. Prior to the operation, the ETS was 3.65±1.6, and at two weeks post-operation, the mean ETS was 4.38±1.6, and showed a statistical improvement. At 1 and 3 months post-operation, the mean ETS went up to 7±1.39 and 7.41±1.89 respectively. Compared to pre-operation levels, ETS showed a quick improvement during the first month post-operation. The clicking noise triggered by swallowing, indicating ET opening was present in 19 cases (one case at all times and 18 cases with infrequent episodes) at two weeks post-operation. However, after the 1st and 3rd month post-operation, there were 27 cases (6 cases at all times and 21 cases with infrequent episodes) and 31 (16 cases at all times and 15 cases with infrequent episodes), respectively. For 3 cases, no clicking noise was present when swallowing. The Scheffé statistic test showed significant differences ($P < 0.05$) between the mean ETS pre-BET and follow-up examinations after 2 weeks, 1 and 3

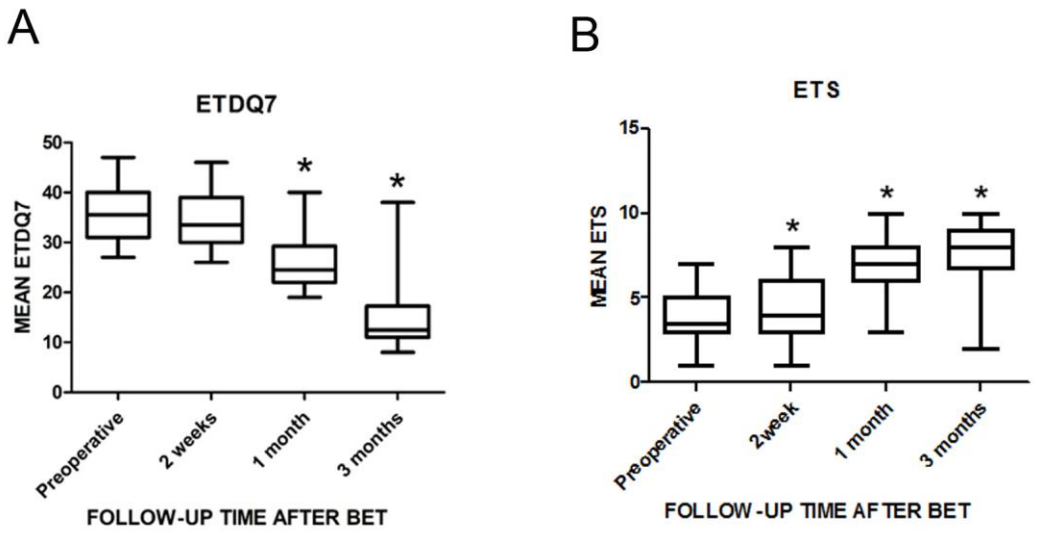

Figure 3: Means and standard deviations of ETDQ-7 ad ETS. A. ETDQ-7 means and standard deviations of pre- and postoperatively follow-up examinations after 2 weeks, 1 month and 3 months. All follow-up values were significant compared to preoperative ETDQ7 scores except at 2 weeks (*p < 0.05, Scheffé test). B. Eustachian tube score (ETS) means and standard deviations at pre- and postoperative follow-up examinations at 2 weeks, 1 month and 3 months. All follow-up values were significant compared to preoperative ETS (*P < 0.05, Scheffé test).

Table 3: Preoperative and postoperative results of tympanogram.

Type of tympanometry	Number of ears preoperative (%)	Number of ears postoperative(%)		
		2 weeks	1 month	3 months
A	0	0	3 (8.8)	9 (26.5)
B	28 (82.4)	25 (73.5)	13 (38.2)	5 (14.7)
C	6 (17.6)	9 (26.5)	18 (58.9)	20 (58.8)
p[a]		=0.385	<0.05*	<0.01*

p[a] McNema.
* compare with preoperative.

months (Figure 3B).

Post operation evaluation by tympanogram

Tympanogram did not show statistical improvement until one month post-operation (Table 3). Prior to the operation, type B tympanogram was observed in 28 ears (82.4%) and type C tympanogram was observed in 6 ears (17.6%). At 2 weeks post-operation, type B tympanogram was observed in 25 ears (73.50%) and type C tympanogram was observed in 9 ears (26.5%). Statistical analysis showed no significant differences (p>0.05). At 1-month post operation follow-up, type A tympanogram was observed in 3 ears (8.8%), type B tympanogram was observed in 18 ears (52.9%) and type C tympanogram was observed in 13 ears (38.3%). Statistical analysis showed significant differences (p<0.05). At three months post operation follow-up, type A, B and C tympanogram was observed in 9 ears (26.5%), 5 ears (14.7%) and 20 ears (58.8%), respectively and showed significant differences as compared with pre-operation tympanogram results (p<0.01). Based on tympanogram, improvement at two weeks after BET was 8.8% (3/34), while improvement for the 1st and 3rd month after BET was 29.4% (10/34) and 67.6% (23/34), respectively. In comparing improvements among the different evaluation methods, we found ETS was the most sensitive, and showed improvement at the 2-week follow-up period. However, the changes in ETS did not relieve symptoms. We observed reduced statistical significance of ETDQ-7 at 1-month post-operation follow-up.

DISCUSSION

Treatment for ET dysfunction is mainly via myringotomy and tympanostomy tube placement into the tympanic membrane (TM). This is done to equalize middle ear

pressure and drain fluid via the TM bypassing the ET. This approach has advantages in relieving symptoms but does not treat the underlying ET dysfunction. The bony isthmus is the narrowest part of the tubal canal and is the primary target site for ET dysfunction. To increase the diameter of the narrow canal, endoscopic transnasal surgery combined with inflatable balloons (used in cardiac surgery) was developed by Yamashita in an attempt to correct chronic ET dysfunction. This has led to the development of more advance instruments, such as the flexible fiberscope for insufflation of air to expand the tubal lumen (Yamashita, 1983). Further progressive miniaturization of the flexible fiberoptic system has made it possible to perform nontraumatic endoscopy of the ET and tympanic cavity, keeping the ear drum intact (Hopf, 1991). The safety and efficacy of this procedure has been reported in several studies (Schroder et al., 2014). Evaluation of treatment outcomes is difficult, since there are no consensus standards for the assessment of post-operation efficacy. Different diagnostic approaches make it difficult to evaluate the efficacy of BET. However, several approaches are not used routinely due to limited data on their reliability, while some approaches are invasive and expensive. To-date, the most common approach is tympanometry, ETDQ-7 and tubomanometry.

Tympanometry is a standard method to evaluate pressure differences behind the tympanic membrane and it indirectly reflects the function of the ET. However, this test requires an intact tympanic membrane and is complex and time-consuming. There are three types of tympanogram, but they are unable to quantify ET function accurately. On occasions where the tympanic membrane is thick or effusion is low, the results could be misinterpreted.

McCoul et al. (2012) developed the ETDQ-7, a new questionnaire that could be used to diagnose and assess ET dysfunction (McCoul, 2012). Several studies have demonstrated that ETDQ-7 is very reliable and is valid to clinically assess ET function (Schroder et al., 2015b). However, it only focuses on subjective complaints of patients and does not include any objective data. In addition, since the questionnaire has only 7 levels for each symptom, it is difficult to make a judgement based on subtle changes after operation.

Tubomanometry is an objective, reproducible and accurate test method to diagnose ET dysfunction. The complete examination of both ears takes about 5 min in the hands of an experienced technician. An R-value ≤1 indicates a regular function of the ET, an R-value >1 indicates a delayed opening of the ET, and no definable R-value denotes no detectable opening of the ET. With its high sensitivity and specificity, this method is ideal for BET evaluation. Another distinct advantage of TMM is that it works in intact as well as perforated eardrums. Schroder et al. (2015c) indicated that TMM measures not only the function of the ET but also the whole gas transfer by the ET and the mucosa of the mastoid. Hence it is a reliable and a valid instrument to evaluate the effect of BET.

Although tubomanometry is easy to perform and can perform evaluations quickly, some studies have shown that the R value was not a reliable measure of ET opening. Having the proper settings to calculate the R-value is critical or measurements may give a false negative. For example, when there is middle ear effusion, or significant negative pressure, tubomanometry is unable to detect TM movement. This could lead to an undetectable R value, implying poor ET function (Di Martino, 2013). A previous study showed that the R value is sensitive in detecting the ET opening but is not specific. This is due to the high proportion of false positives using the criteria of >5 daPa (0.43) or >10 daPa (0.41) (Silvola, 2014). The ETS contains three tubomanometric measurements and two subjective estimations for clicking noise when swallowing and positive Valsalva's maneuver. The sensitivity and specificity have been reported to be as high as 91 and 86%, as compared with tubomanometry only, which was able to diagnose an ETD cohort with a sensitivity of 49% and specificity of 93% for opening threshold measurements, and a sensitivity of 87% and specificity of 67% for latency measurements (Smith and Tysome, 2015).

Our study demonstrated that the R value is highly sensitive for post BET evaluation. It can detect rapid improvements in ET opening as early as 2 weeks after BET. However, ETDQ-7 indicated patient symptom relief only at the 1st month after BET and was consistent with tympanometry. The patient who received secondary operation had an improved R value, but showed no improvement in ETS. This indicates that ETS may be more suitable for long term evaluation after BET. However, we found a significant correlation between the results from different investigators and different times of investigation. This was consistent with the study performed by Sudhoff et al. (2009). Hence, we believe ETS should not be used as the only method for effective evaluation after BET. Additional studies are required to determine its precision, stability and reliability.

ACKNOWLEDGEMENT

This work was supported by grants from the Medical and Health Technology Planning Project of Zhejiang Province (2019KY233).

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