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Efficacy of balloon dilation in the treatment of symptomatic Eustachian tube dysfunction: One year follow-up study

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ABSTRACT

Purpose: Eustachian tube balloon dilation (ETBD) has been recently described as feasible treatment for patients with refractory Eustachian tube dysfunction (ETD). The aim of this study was to evaluate the efficacy of ETBD in the treatment of symptomatic Eustachian tube dysfunction (SETD) by subjective and objective analysis.

Materials and methods: Forty patients who underwent ETBD were included in the study. Subjects' inclusion criteria were as follows: symptoms of ETD (aural fullness predominantly, with or without otalgia, muffle hearing and tinnitus), normal tympanic membrane, type A or C tympanograms, and without a history of any middle ear diseases. Main outcomes including subjective improvement, otoscopy, pure-tone audiometry, impedance audiometry, R-value in tubomanometry (TMM) at three pressure measurements (30, 40, and 50 mbar), Eustachian Tube Score (ETS) and the ability to perform a Valsalva maneuver were assessed preoperatively, 1 week, 3 months and 12 months postoperatively.

Results: All cases were dilated successfully. A significant effect of treatment was documented when measuring subjective improvement, impedance audiometry, R-value in TMM, ETS and the ability to perform a Valsalva maneuver 1 week, 3 months and 12 month postoperatively. Subjective symptoms were not relieved only in one patient. The overall success rate for all patients was 98%.

Conclusions: ETBD can provide both short- and long-term benefits to those who are diagnosed SETD and refractory to medical management. SETD might be an optimal indication for ETBD in the treatment of ETD.

1. Introduction

The Eustachian tube (ET) is a complex osseocartilaginous tube that links the nasopharynx and the middle ear. Under regular conditions, the ET is closed and it opens only on swallowing, yawning, sneezing and the Valsalva maneuver to act as a pressure-equalizing valve for the middle ear. It also serves to drain the mucus produced by the lining of the middle ear.

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Eustachian tube dysfunction (ETD) is the inability of the ET to adequately ventilate the middle ear. Patients with ETD often complain of aural fullness, otalgia, muffle hearing, tinnitus and hearing loss. ETD is common and estimated to have a prevalence of about 1% in the adult population [1]. Although there are a number of medical and surgical treatment options aimed at improving ED function, the treatment of ETD in adults is often less satisfactory [2,3]. ETD can be treated primarily with a combination of active observation, autoinsufflation and nasal steroids, but these therapeutic methods to improve ETD often show limited success [4]. A recent study showed that steroid nose spray does not improve ETD symptoms compared to placebo [5]. Tympanostomy tube placement can equalize meddle ear pressure and improve patients' symptoms, but nevertheless it undoubtedly increases risks of complications such as perforation, otorrhea, tympanosclerosis, and even cholesteatoma [6]. Recently, balloon dilation of the ET (ETBD) has emerged as a potential therapeutic option and shown promising short-term results, at least [7–12]. However, patients with ETD enrolled in these studies included those who had concomitant middle ear diseases, such as otitis media with effusion (OME), or had a previous history of chronic suppurative otitis media or cholesteatoma. These preoperative middle ear statuses might compromise the therapeutic effect of ETBD.

The aim of the present study is to evaluate long-term outcomes of ETBD on patients that presented with symptomatic Eustachian tube dysfunction (SETD).

2. Materials and methods

After an exclusion of temporomandibular joint disease and early endolymphatic hydrop, patients who complained of aural fullness (with or without otalgia, muffled hearing and tinnitus) with normal tympanic membrane for at least 6 months, without OME, middle ear atelectasis and a history of any middle ear diseases were diagnosed as SETD. Patients who were admitted to our hospital between April 2013 and November 2014 with SETD and treated with ETBD were retrospectively analyzed. The study was approved by the ethical review board of Sun Yat-sen Memorial Hospital, Sun Yat-sen University, China, and informed consent was obtained from all participants.

Patients were assessed by history, otoscopy, pure-tone audiometry (125, 250, 500, 1000, 2000, 4000 and 8000 Hz), impedance audiometry, R-value in tubomanometry (TMM) at three pressure measurements (30, 40, and 50 mbar), Eustachian Tube Score (ETS, range, 0 to 10, a value of 5 or less is regarded as a sign for ETD) as introduced by Ockerman et al. [10] and the ability to perform a Valsalva maneuver. The ETD symptoms were examined with a visual analogue scale (VAS) questions focusing on aural fullness, otalgia, muffle hearing and tinnitus (range, 0 to 10, with higher scores indicating more severe symptoms). All these parameters were recorded preoperatively, 1 week, 3 months and 12 months postoperatively. In addition, a high-resolution computed tomography (HRCT) of temporal bone was obtained for each patient to exclude bony dehiscence of the carotid artery and anomalies of the ET.

The surgical technique for ETBD has been described in detail in previous reports [8,10,12]. In all cases, the procedures were done under general anesthesia. The balloon catheter (Spiggle & Theis GmbH, Germany) was inserted into the ET with endoscopic assistance (30-degree view angle). The balloon (20 mm in length and 3.28 mm in diameter) was inflated with sterile water to a pressure of 10 bars for 2 minutes.

The results were analyzed using SPSS 16.0. (Chicago, IL). The pairs-samples T-test and the Wilcoxon signed-rank test were used to compare pre- and postoperative data. A p value of less than 0.05 was considered to be statistically significant.

3. Results

ETBD was performed on 58 ETs in 40 patients with a mean age of 42 years (range 21–70 years). The duration of symptoms was between 14 and 86 months (mean 45 month years). 43 percent procedures were on the left, 57 percent procedure were on the right. 53 percent of patients were male, and 47 percent were female. All patients experienced aural fullness of different magnitudes, 55% had muffle hearing, 33% had otalgia and 36% had tinnitus. Ten patients aged from 55 to 70 years showed slight to moderate sensorineural hearing loss (hearing threshold between 25 and 55 dB) at 4000 and 8000 Hz by means of pure tone audiometry. Other patients had normal hearing at all tested frequencies. No hearing threshold shift was found after ETBD and during follow-up. All patients had been treated with autoinsufflation, topical decongestant, antihistamine and nasal steroids for at least 6 months prior to recruitment and showed no response to conservative management. No bony carotid canal dehiscence was found by HRCT.

All cases were dilated successfully, without significant complications. The pre- and postoperative subjective and objective results are presented in Table 1. Subjective postoperative improvement of symptoms (aural fullness, predominantly) was perceived by 30 (88%) patients at 1 week, 38 (95%) patients at 3 months and 39 (98%) patients at 12 months postoperatively. Aural fullness sensation completely disappeared in 83% of cases (48/58 ears) at 12 months postoperatively and no incidence of relapse was found. Otoscopy showed normal findings in tympanic membrane preoperatively and there was no obvious alteration at follow-up 1 week, 3 months or 12 months postoperatively. Type A tympanogram was more frequently observed in the patients while type C tympanogram was presented in 26% of cases (15/58 ears) preoperatively. After ETBD, the conversion of type A tympanogram was present in 33% of cases (5/15 ears), 47% of cases (7/15 ears) and 93% of cases (14/15 ears) at 1 week, 3 months and 12 months postoperatively, respectively. For the ETS, a significant improvement was observed at 1 week, 3 months and 12 months postoperatively. The positive ability to perform a Valsalva maneuver was improved in 39 patients who failed to do it preoperatively at 12 months postoperatively. Only one patient with one ear showed no response to ETBD. The overall success rate for all patients was 98% (57/58 ears).