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Clinical Report

Responsiveness of the 7-item Eustachian Tube Dysfunction Questionnaire

Shari Van Roeyen, Paul Van de Heyning, Vincent Van Rompaey

Antwerp University Hospital, Otorhinolaryngology and Head and Neck Surgery, Edegem, Belgium (SVR, PVDH, VVR)
University of Antwerp, School of Medicine and Health Sciences, Wilrijk, Belgium (SVR, PVDH, VVR)

OBJECTIVE: Baro-challenge-induced Eustachian tube (ET) dysfunction is defined as the presence of aural discomfort, popping, or pain, which only arises in case of ambient pressure changes, without abnormalities on otoscopy or tympanometry. Our primary aim was to determine the discriminative power of the 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) in patients with baro-challenge-induced ET dysfunction in comparison with that in healthy controls. The secondary aim was to determine the responsiveness of ETDQ-7 in patients with baro-challenge-induced obstructive ET dysfunction who underwent balloon dilation tuboplasty (BDET).

MATERIALS and METHODS: The accuracy of the diagnostic test was determined on the basis of the area under the curve in receiver-operating curve (ROC) analysis. Responsiveness to change of ETDQ-7 was assessed by exploring preoperative and postoperative ETDQ-7 scores using Cohen's kappa coefficient. Patients were asked whether their complaints improved, remained stable, or deteriorated after BDET. The findings of subjective evaluation were then compared with the difference in the ETDQ-7 score after BDET.

RESULTS: In the baro-challenge-induced ET dysfunction group, the median preoperative total ETDQ-7 score was 26, decreasing to 16 after BDET. ROC analysis demonstrated excellent discriminative power for the baro-challenge-induced ET dysfunction group. Cohen's kappa coefficient was 0.633, indicating that there was substantial agreement between the ETDQ-7 values before and after BDET.

CONCLUSION: ETDQ-7 can discriminate between patients with baro-challenge-induced ET dysfunction and healthy controls and can therefore be useful in its diagnosis. Furthermore the ETDQ-7 is responsive to change in patients with baro-challenge-induced ET dysfunction who have undergone BDET, although a larger sample size is required to confirm these preliminary findings.

KEYWORDS: Surveys and questionnaires, Eustachian tube, barotrauma

INTRODUCTION

Obstructive dysfunction of the Eustachian tube (ET) is defined as the inadequacy of ET to ventilate the middle ear. This may result in retraction or atelectasis of the tympanic membrane or chronic otitis media, which can be evaluated by otoscopy and tympanometry. However, symptoms of aural fullness, popping, discomfort, or pain may only arise in case of ambient pressure changes, without abnormalities detected on otoscopy and tympanometry. This subtype is called baro-challenge-induced ET dysfunction [1]. Recently, balloon dilation Eustachian tuboplasty (BDET) has been demonstrated to be effective in 70% of a large cohort of patients affected by obstructive ET dysfunction [2, 3].

The 7-Item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) was designed by McCoul et al. [4] as a disease-specific instrument for the assessment of symptoms related to obstructive dysfunction of ET. Although ETDQ-7 can discriminate between patients with any type of ET dysfunction and controls, it cannot discriminate between patients with patulous ET dysfunction and those with obstructive ET dysfunction (even without including a question on autophony) [5, 6]. In addition, its responsiveness to change after (medical or surgical) treatment has not been studied.

The first aim was to determine the discriminative power of ETDQ-7 in patients with baro-challenge-induced ET dysfunction and healthy controls. The second aim was to determine the responsiveness of ETDQ-7 to change after treatment in patients with baro-challenge-induced obstructive ET dysfunction who underwent BDET.

MATERIALS and METHODS

Ethics

The study was designed and conducted according to the Declaration of Helsinki (1996). Ethical committee approval was obtained. Written informed consent was not deemed necessary by the ethics committee.

Corresponding Address: Vincent Van Rompaey E-mail: vincent.van.rompaey@uza.be

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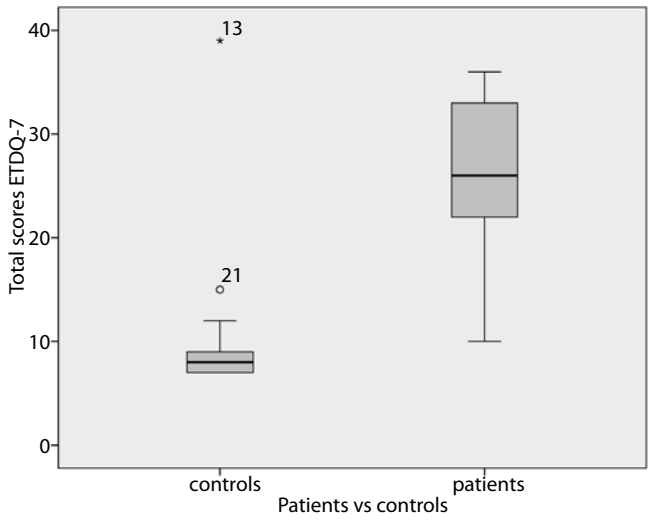

Figure 1. Baseline total ETDQ-7 scores of the baro-challenge-induced ET dysfunction group (patients) versus the healthy control group (controls)

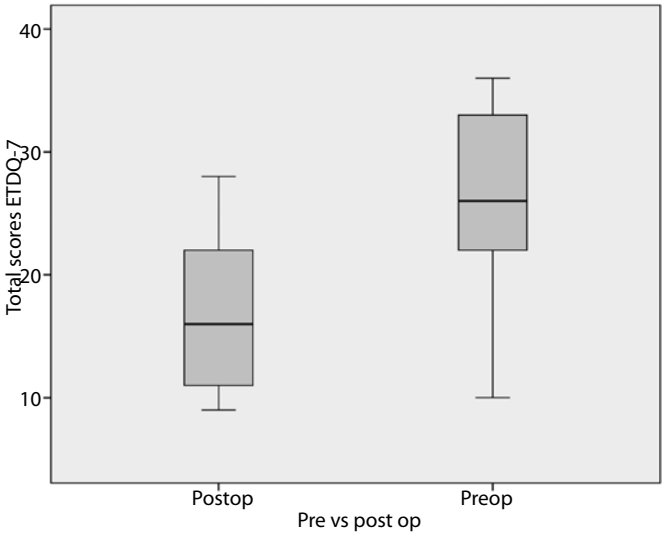

Figure 2. Total ETDQ-7 scores of the baro-challenge-induced ET dysfunction group before and after surgery. Preop: preoperative; Postop: postoperative

Patient Group

Inclusion criteria for baro-challenge-induced obstructive ET dysfunction were history of aural fullness, popping in the ear or discomfort produced by ambient pressure changes; normal otoscopy, normal tympanometry, and normal liminal audiometry [1]. Symptoms had to be incapacitating and refractory to a 3-month empirical trial of topical nasal corticosteroids and oral antihistamines.

Control Group

The baseline ETDQ-7 scores in the present patient population were previously compared with those in the control group by our group [5].

Surgical Technique

BDET was performed using the Bielefeld balloon catheter (Spiggle & Theiss GmbH; Overath, Germany), following the standard surgical procedure [2].

Accuracy Testing

SPSS was used for statistical analysis (IBM SPSS Statistics for Windows, Version 22.0.; Armonk, NY: IBM Corp.). Accuracy was determined using hte area under the curve (AUC) in receiver-operating curve (ROC) analysis. AUC exceeding 0.9 was defined as excellent, 0.8-0.9 as good, 0.7-0.8 as fair, 0.6-0.7 as poor, and 0.5-0.6 as failed.

Responsive Measures. Responsiveness to change of ETDQ-7 was assessed by exploring preoperative and postoperative ETDQ-7 scores using Cohen's kappa coefficient. Patients were asked whether their complaints improved, remained stable, or deteriorated after BDET. The findings of subjective evaluation were then compared with the difference in the ETDQ-7 score after BDET. Cohen's kappa values were defined as follows: 0, no agreement; 0-0.20, slight agreement; 0.21-0.40, fair agreement; 0.41-0.60 moderate agreement; 0.61-0.80, substantial agreement; and 0.81-1, almost perfect agreement.

RESULTS

Eight patients with baro-challenge-induced ET dysfunction underwent bilateral BDET, and 3 patients unilateral BDET. The patients with baro-challenge-induced ET dysfunction and the control group had a mean age of 49 years (ranging from 21 to 86 years) and 36 years (ranging from 21 to 60 years), respectively. The baro-challenge-induced ET dysfunction group included 7 male (64%) and 4 female (36%) patients, while the control group included 8 males (36%) and 14 females (64%).

The baseline scores of the baro-challenge-induced ET dysfunction group were higher than those of the control group (Mann-Whitney U test; $p<0.001$) (Figure 1). AUC in ROC analysis for the baro-challenge-induced ET dysfunction group was 94.3%, confirming its excellent discriminative power toward the healthy control group.

The median total ETDQ-7 score in the control group was 8 (ranging from 7 to 39). In the baro-challenge-induced ET dysfunction group, the median preoperative total ETDQ-7 score was 26 (ranging from 10 to 36). This score decreased to 16 (ranging from 9 to 28) after BDET (Figure 2). In the subjective appreciation of the evolution of their symptoms after BDET, 5 patients reported stable symptoms, while the other 6 patients reported a subjective improvement. No patient experienced worsening.

Cohen's kappa coefficient, the measure of responsiveness to change, was 0.633, indicating that there was substantial agreement between the ETDQ-7 values before and after BDET.

DISCUSSION

In patients with baro-challenge-induced ET dysfunction, by definition, no abnormalities are observed on otoscopy or tympanometry, which means that its diagnosis is based on patient-reported symptoms and the clinician's expert opinion [1]. Because of this lack of objective measures, a validated disease-specific instrument may help in discriminating between patients with ET dysfunction. McCoul et al. [4] reported their ETDQ-7 to reliably discriminate between patients with obstructive ET dysfunction and healthy controls. However, Van Roeyen et al. [5] later demonstrated that ETDQ-7 (even without the item *autophony*) cannot discriminate between obstructive and patulous ET dysfunction [5, 6]. ETDQ-7 can thus assess symptom severity, but still, expert opinion is essential for discrimination. Therefore, the primary aim of the present study was to evaluate whether the ETDQ-7 can discriminate between patients with baro-challenge-induced

ET dysfunction and healthy controls because the former group presents with relatively mild symptoms. ROC analysis in the present study demonstrated that ETDQ-7 leads to excellent discrimination between patients with baro-challenge-induced ET dysfunction and healthy controls. Therefore, ETDQ-7 can be useful in the diagnostic process of baro-challenge-induced ET dysfunction.
A potential criticism of ETDQ-7 is the lack of data on its responsiveness to change after treatment. Therefore, our secondary aim was to study its potential to detect change after BDET in patients with persisting symptoms after empirical medical treatment. Cohen's kappa analysis demonstrates that the responsiveness of ETDQ-7 to change after treatment with BDET is substantial in the baro-challenge-induced ET dysfunction group. Whether these data can be extrapolated to acute or chronic obstructive ET dysfunction or patulous ET remains to be studied.

The major limitation of our study is mainly its small sample size and the absence of a gold standard. Further research is required to determine its responsiveness in case of other types of obstructive and patulous ET dysfunction and to determine whether the ETDQ-7 scores are higher in patients with unilateral or bilateral ET dysfunction.

In conclusion, this study provides evidence that ETDQ-7 can discriminate between patients with baro-challenge-induced ET dysfunction and healthy controls. Furthermore, ETDQ-7 is responsive to change in patients with baro-challenge-induced ET dysfunction who have undergone BDET, although a larger sample size and longer postoperative follow-up are required to confirm these preliminary findings.

Ethics Committee Approval: Ethics committee approval AGA085 applied to this study.

Informed Consent: Written informed consent was not deemed necessary by the ethics committee.

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