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Original Paper

Balloon Dilatation of the Eustachian Tube: Postoperative Validation of Patient Satisfaction

F. Bast[a] A. Frank[b] T. Schrom[b]

[a]Craniofacial Unit, Chelsea and Westminster Hospital, London, UK; [b]Clinic for Otorhinolaryngology, Head and Neck Surgery/Plastic Surgery, Helios Clinics Bad Saarow, Bad Saarow, Germany

Key Words
Glasgow Benefit Inventory · Eustachian tube · Outcomes research · Balloon dilatation · Eustachian tube dysfunction

Abstract
Objectives: The Eustachian tube is responsible for ventilation, protection and drainage of the middle ear. Dysfunction of the Eustachian tube can lead to impairments ranging from inadequate pressure equalisation in the middle ear and pneumatised mastoid process to cholesteatoma. Conventional surgical interventions for chronic tube dysfunction have not brought resounding clinical success. However, the 'Bielefelder Balloon dilatation' constitutes a new and, judging from early results, very effective treatment for chronic tube dysfunction. Proof of the efficacy of the surgical procedures is provided by objective clinical factors, but for quality assurance, the assessment of the subjective quality of life of patients must also be taken into account. To measure health-related quality of life, standardised questionnaires are used which have been tested for reliability, validity and sensitivity. ***Methods:*** A total of 30 patients were included in the study. The patient survey was conducted retrospectively, and validation of patient satisfaction was carried out with the Glasgow Benefit Inventory (GBI). ***Results:*** GBI analysis revealed significant improvements in the total score as well as in general and physical health. ***Conclusions:*** The Bielefelder Balloon dilatation is a new and safe treatment for chronic tube dysfunction, which had a significant positive influence on the postoperative quality of life of our patient cohort.

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Dr. med. Florian Bast
Craniofacial Surgery
Chelsea and Westminster Hospital
369 Fulham Road, London SW10 9NH (UK)
E-Mail Florianbast@gmx.de

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Introduction

One of the best descriptions of the connection between the nasopharynx and middle ear dates back to Aristotle, who saw its primary function as the transmission of echoes from the ear to the heart. This theory was challenged by the more precise anatomical and physiological description of the Eustachian tube by the Italian physician Bartolomeus Eustachius in 1562, which dramatically changed our understanding of this structure [1, 2].

The Eustachian tube is responsible for ventilation, protection and drainage of the middle ear. Ventilation involves both gas exchange and the regulation of pressure equalisation. In addition to carrying out the internal mucocilliary transport of secretions, the tube can also be opened by activating the musculus tensor veli palatini. Closure of the Eustachian tube involves the elasticity of the tubal cartilage, the so-called Ostmann fatty tissue, blood vessels in the mucous membrane and peritubal tissue pressure. A dysfunction of the Eustachian tube, especially an obstruction, results in faulty pressure conditions in the middle ear and pneumatised mastoid process. In addition to complaints, such as an unpleasant sensation of pressure or fullness in the affected ear, tube ventilation dysfunction is often accompanied by chronic middle ear infections, with or without cholesteatoma [1, 3–7].

While acute tube dysfunction is mainly treated conservatively with medication to decrease swelling in the nasal mucus membranes, the administration of secretolytics and the use of active pressure equalisation manoeuvres in chronic tube dysfunction does not respond to these therapies. With the previously available surgical measures, such as repeated insertion of tympanostomy tubes, tube conductors (silicon hoses or gold tubal wires), complex transmastoidal shunt operations or laser tuboplasty, good clinical outcomes have been elusive [1, 2, 8–10].

The 'Bielefelder balloon dilatation', a new, safe and, judging from early results, very effective treatment for chronic tube dysfunction has been available only since a few years. It involves the transnasal endoscopic introduction of a balloon catheter through the nasopharyngeal opening of the Eustachian tube into the hole tube, where the balloon is dilated for 2 min at a pressure of 10 bars [10–15].

The overall success of a medical or surgical intervention cannot be judged exclusively by the degree of technical success and positive postoperative diagnostics. Changes in the quality of life of the patient resulting from a specific treatment also have to be taken into account. Various validated quality of life measurements are available for this purpose [16–20].

As of yet, the only questionnaire specifically for ear problems available in German is the Chronic Otitis Media Outcome Test 15 by Baumann et al. [21]. This questionnaire measures health-related quality of life in patients with chronic otitis media, but its 15 questions do not explicitly address tube dysfunction [21].

General measurement instruments worth mentioning include the 'Short Form 36 Health Survey', the 'Short Form 12 Health Survey', the 'European Quality of Life 5 Dimensions' as well as the Glasgow Benefit Inventory (GBI) developed especially for the field of ear, nose and throat (ENT) [16]. The GBI consists of 18 questions and was introduced in 1996 as a postoperative measurement tool for reflecting changes in health status following surgical or conservative treatments. The definition of health status according to the GBI is the general perception of one's own health, including psychosocial, social and physical factors. As a postoperative measurement instrument, the GBI is designed for maximum sensitivity to changes in health status and has been often used in the literature [16, 22].

Using the GBI, the present study aims to validate general quality of life following balloon dilatation of the Eustachian tubes.

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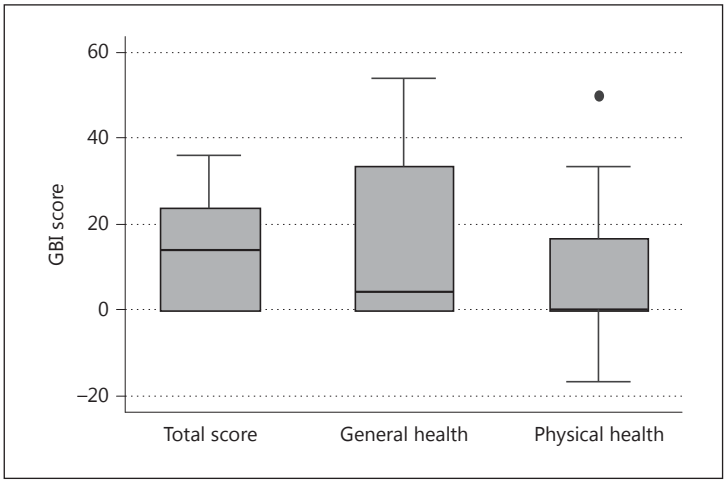

Fig. 1. GBI scores with significant improvement of the total score as well as the general and physical health scores.

Materials and Methods

Each patient who was in our hospital between September 2011 and September 2012 and underwent a transnasal endoscopic balloon dilatation of the Eustachian tube under general anaesthesia due to a chronic tube ventilation dysfunction was retrospectively sent a standardised questionnaire regarding patient satisfaction. The response rate, following an additional reminder mailing, reached 88%. A total of 30 patients were included, 11 men and 19 women, with an average age of 49.7 years (ranging from 24 to 73). The postoperative observation period was between 6 and 18 months. Validation of patient satisfaction was carried out with the GBI.

Contraindications for the balloon dilatation of the Eustachian tube were age under 18 years, a preoperative unidentifiable nasopharyngeal opening of the Eustachian tube, a lack of bony covering of the internal carotid artery, a severe septal deviation and hyperplastic turbinates as well as contraindications against general anaesthesia. After signing a consent form, the operation was always performed by the same surgeon and carried out according to specified standard techniques. Instruments from the company Spiggle & Theis were used. As part of the diagnostics and as a pre-examination, every patient underwent a clinical examination, audiometry, tympanometry and a thin-layer CT of the petrosal bone [11, 12].

Statistical analysis was done in cooperation with the Office of Applied Statistics (p-Wert, Witten, Germany). To describe the metrical variables, the following variables were used: number, average, standard deviation, extrema, quartile and median. The distribution of categorical and ordinal data was described in terms of absolute and relative frequency. The sign test was used to determine whether the medians of the scores differ significantly from zero. This non-parametric test is preferred over the t test because of the numerous combinations (same values) of the scores. The tests were calculated bilaterally at $p = 0.05$.

This study was approved by the Medical Association and Ethics Committee of Cottbus, Germany.

Results

The analysis of the 18 GBI questions showed a significant improvement in the total score ($p = 0.001$), in the subscore ‘general health’ ($p = 0.001$) and in the subscore ‘physical health’ ($p = 0.039$) (fig. 1). Thus, the medians of all three variables differed significantly from zero. Since all scores except one in the subscore ‘social support’ were zero, no test was done on this score.

Hence, with GBI as a general measurement tool, a significant improvement in general and physical health following balloon dilatation could be shown.

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Discussion

The significance of the auditory tube is highlighted when chronic ear diseases develop. On the one hand, it protects against secretions and acoustic pressure from the nasopharynx, and on the other hand, it drains mucus from the middle ear cavities. However, the auditory tube has a very important task, functioning as a valve for equalising middle ear and atmospheric pressure. Chronic tube dysfunction and accompanying chronic middle ear problems do not respond to conservative treatment. Symptomatic treatments traditionally include paracentesis and a tympanostomy tube. In addition, the possibilities of tube dilatation, drainage or laser tuboplasty have been explored without any resounding clinical success [1, 2, 4, 8, 9].

The Bielefelder balloon dilatation has been available only since a few years and constitutes a new, safe, and according to early results, very effective treatment for chronic tube dysfunction. The 2-cm-long balloon is placed in the cartilaginous part of the auditory tube, and thus the whole cartilaginous section can be treated with this procedure [10–12].

Not only the treatment of chronic tube dysfunction but also its diagnostics are difficult. At the moment, there are only three simple, practicable clinical methods for diagnosing diseases of the Eustachian tube: ear microscopy with the Valsalva manoeuvre, pneumatic otoscopy and the Toynbee manoeuvre. There are also a few diagnostic procedures that require significantly higher costs and effort (e.g. tympanometry and the tube manometry). Other procedures include the Aspiration-Deflation Test, the Inflation-Deflation Test, the PSTV-Test (politzerisation, swallowing, Toynbee, Valsalva), measuring impedance in the pressure chamber as well as the modified tube manometry by Estève. Additionally, attempts to visualise the tube function are made with technologies such as MRI, sonotubometry or ventilation scintigraphy [4, 5, 10, 14, 23, 24].

However, none of these procedures alone is capable of reproducing the complexity of the functional anatomy or physiology of the tube [5, 25]. For this reason, it is also difficult to measure the improvement of tube function after endoscopic dilatation. As a result, we decided to use the GBI, a tool specially designed for health problems and interventions in the field of ENT, to measure postoperative changes in quality of life [16].

If this questionnaire is analysed according to Cella's [26] concept of quality of life, which is geared to patients and addresses health-related questions, it is clear that all four dimensions (psychosomatic, functional, social and psychological-emotional) are investigated. The psychosomatic dimension (i.e. pain) as well as the functional (i.e. daily activities) and the social dimension (relationships with family and friends) are covered by the 18 questions. The psychological-emotional dimension as a part of health-related quality of life is also included in the GBI. Questions regarding fear, depression and sadness fall under this category. Thus, the GBI fulfils the requirement that a measurement instrument must reflect at least three of the four dimensions [26].

An analysis of the GBI results shows a significant improvement in the total score and the subscores 'general health' and 'physical health' following balloon dilatation. This provides evidence that balloon dilatation, with its significant improvement in general and physical health, also leads on the whole to a subjectively improved quality of life.

Conclusion

Dysfunction of the Eustachian tube can cause problems ranging from an inadequate equalisation of pressure in the middle ear and pneumatic mastoid process to cholesteatoma. Traditional surgical procedures for chronic tube dysfunction have not met with resounding clinical success. The GBI is specially designed for problems and procedures in the field of ENT.

An analysis of the GBI results shows a significant improvement in the total score and the subscores 'general health' and 'physical health' following balloon dilatation. Thus, the Bielefelder balloon dilatation procedure, constitutes as new, safe, and according to early results, very effective treatment for chronic tube dysfunction.

Disclosure Statement

The authors have no conflicts of interest and no financial relationships with the relevant commercial interests. The study was financed by the HELIOS Research support ID 004974.

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