

# Effect of type 1 tympanoplasty on health-related Quality of Life assessed by Chronic Otitis Media Questionnaire 12

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**Abstract. – OBJECTIVE:** The aim of the study was to evaluate the changes in the quality of life of patients who underwent Type 1 tympanoplasty using the Chronic Otitis Media Questionnaire 12 (COMQ-12).

**SUBJECTS AND METHODS:** Prospectively collected data of patients aged between 18-65 years, who had undergone type 1 tympanoplasty between January 2018 to January 2019 were included in the study. The Turkish version of COMQ-12 was completed by all of the patients preoperatively as well as 12 months postoperatively. Preoperative and postoperative graft uptake outcomes, hearing assessment results, and scores of COMQ-12 were evaluated. Shapiro-Wilk test, Mann-Whitney U test, and Wilcoxon test were used.

**RESULTS:** A total of 98 patients were included. Noticeable improvement in the severity of symptoms, negative effect on daily life and work routine, health care, and general well-being was detected by subjective scores of the questionnaire. The COMQ-12 preoperative and postoperative overall average score was 25 and 7, respectively ( $p<0.001$ ). Graft uptake success was found to be 85%. Hearing assessment evaluation showed a mean change in air conduction values of 8.78 (SD 1.17), and a mean change in air-bone gap values of 7 (SD 0.8), both showing statistical significance ( $p<0.001$ ).

**CONCLUSIONS:** According to the COMQ-12 questionnaire data after surgery, symptom severity, lifestyle and work impact, health service impact, and general discomfort were significantly reduced.

## Key Words:

Chronic otitis media, Chronic Otitis Media Questionnaire-12, Hearing loss, Quality of life, Type-1 tympanoplasty.

intermittent otorrhea. It is a widespread disease that continues to be a major public health issue regardless of all scientific progress<sup>1</sup>. It is seen approximately in 2% of the population worldwide, and its prevalence may range up to 4% in developing countries<sup>2,3</sup>.

COM is associated with frequent hospital visits and significant hearing loss. Severe hearing loss may lead to communication problems resulting in withdrawal from social activities<sup>4,5</sup>. All of these may lead to destruction in the common health and well-being of the patients. Additionally, COM may lead to more serious and life-threatening complications such as mastoiditis, labyrinthitis, facial paralysis, hydrocephalus, lateral sinus thrombosis, intracranial abscess, and encephalitis<sup>6</sup>.

Type 1 tympanoplasty or myringoplasty is the procedure where tympanic membrane perforation is repaired without ossicular reconstruction. The main goal is creating an intact, stable grafted membrane with better hearing levels<sup>7</sup>. It is a safe and effective method for preventing continuous infections and improving hearing, building a higher life quality for patients<sup>1</sup>.

In the condition of COM, health-related quality of life (HRQoL) outcome defines the consequences of chronic middle ear infection on physical symptoms, social relations, daily activities, and emotional welfare of patients<sup>8</sup>. The Chronic Otitis Media Questionnaire-12 (COMQ-12) is a newly developed HRQoL questionnaire validated for both preoperative and postoperative use. The COMQ-12 scale's Turkish adaptation is used instead of the original questionnaire with its consistency, reliability, and validity in Turkish studies<sup>9</sup>.

This study aimed to evaluate Type 1 tympanoplasty's surgical outcome in chronic otitis media cases and its relationship with the personal progress experienced by the patients through the COMQ-12 questionnaire.

## Introduction

Chronic otitis media (COM) is an inflammatory middle ear condition presenting with persistent or

## Subjects And Methods

After the Ethical Committee approval (Kartal Dr. Lutfi Kirdar Training and Research Hospital; approval number 2022/514/223/4), prospectively collected medical data of 98 patients aged between 18-65 years, both male and female, who had undergone Type 1 tympanoplasty between January 2018 and January 2019 were analyzed. They were all subjected to pure tone audiometry within one month preoperatively and in the third month postoperatively. Temporal Computerized Tomography (CT) was applied to all of the patients preoperatively. In CT scans, the mastoid aeration of all patients was evaluated as normal.

Surgery was performed under general anesthesia. Incisions were preferred according to the patient's external auditory canal anatomy, either a postauricular or endaural approach was used. Temporal muscle fascia or cartilage-perichondrium composite graft was used with the over-underlay technique in all patients.

The postoperative controls were performed by the same operation team. The surgical performance is measured by otoscopic examinations where graft uptake was evaluated at the 1<sup>st</sup>, 3<sup>rd</sup>, and 12<sup>th</sup> month and hearing assessment at the 3<sup>rd</sup> month after the surgery.

Patients with any retraction pocket along with or without cholesteatoma, ossicular chain dysfunction, related otogenic complications, active infection of the middle ear, and any sign of soft tissue or cholesteatoma in the middle ear cavity or mastoid air cells, as well as patients having pathology in the contralateral ear, were excluded from the study.

COMQ-12 Turkish adaptation form was completed by all of the patients preoperatively and at 1<sup>st</sup> year postoperatively. Postoperative graft success rates were also compared with the scores of COMQ-12. All participants gave their informed consent.

### Statistical Analysis

The distribution of the data was analyzed with the Shapiro-Wilk test. For the comparisons between two independent groups without a normal distribution, the Mann-Whitney U test was used. The comparison of the scale scores before and after the operation was performed by the Wilcoxon test. Descriptive statistics of the data were explained as n (%) for categorical data and median (min-max) for numerical data. The reliability coefficient of the applied questionnaire was calculated with the Cronbach alpha coefficient. All statistical analyzes were

analyzed and reported at a significance level of 0.05 in the IBM SPSS Statistics 28.0 program (IBM Corp., Armonk, NY, USA).

## Results

A total of 98 patients were evaluated; 53 (54%) were female, and 45 (46%) were male, with mean age  $33.47 \pm 12.23$ . Graft uptake was evaluated on follow-up otoscopy at the end of 12<sup>th</sup> month. 83 (85%) of the patients had intact tympanic membranes, whereas 15 (15%) had perforated membranes postoperatively.

The Cronbach  $\alpha$  values calculated for the reliability analysis of the questionnaire applied to the 98 patients in this study were 0.754 for the preoperative symptom complaints sub-dimension, 0.761 for the lifestyle and work-life sub-dimension, 0.774 for the health service influence sub-dimension, and the General Cronbach  $\alpha$  value was 0.838, 0.705 for the post-op symptom complaints sub-dimension, 0.704 for the lifestyle and work-life sub-dimension, 0.689 for health care influence sub-dimension, and General Cronbach  $\alpha$  value was 0.806. Accordingly, it was concluded that the reliability of the questionnaire applied in our study was high according to the preoperative and postoperative Cronbach  $\alpha$  values (Figure 1).

The COMQ-12 preoperative and postoperative overall average score was 25 and 7, respectively ( $p < 0.001$ ). Patients' symptom severity, negative effect on daily life and work, negative effect on health services, and discomfort after surgery were significantly reduced when compared to the preoperative period (Table I).

The total score and sub-dimension scores obtained from the COMQ-12 questionnaire administered to the patients before and after surgery had a statistically significant difference ( $p < 0.001$ ).

In the evaluation of the success of the operation, statistically, there was no significant difference in terms of values of COMQ-12 questionnaire sub-dimension and total scores ( $p > 0.05$ ) (Table II).

The mean air conduction threshold values were preoperatively 37.2 (SD 14.4) and postoperatively 28.4 (SD 3.55). The mean change in preoperative and postoperative values was 8.78 (SD 1.17), which was statistically significant ( $p < 0.001$ ). The mean Air Bone Gap (ABG) value was 23.9 (SD 8.71) preoperatively and 16.9 (SD 10.44) postoperatively; the mean change was 7 (SD 0.8), showing statistical significance ( $p < 0.001$ ) in the current study.

	Pre-op	Post-op
	Mean±sd (min-max)	Mean±sd (min-max)
<b>SEVERITY OF SYMPTOMS</b>		
Ear discharge/drainage	2.47±2.03 (0-5)	0.51±1.05 (0-4)
Having a “smelly ear”	1.80±1.93 (0-5)	0.35±0.83 (0-4)
Difficulty in hearing at home, e.g., turning up the volume of TV or radio	2.72±1.58 (0-5)	1.18±1.42 (0-5)
Difficulty in hearing in crowded places/noisy surroundings or problem in communicating in groups	2.53±1.61 (0-5)	1.18±1.52 (0-5)
Discomfort in and/or around the ear	1.54±1.71 (0-5)	0.58±1.14 (0-5)
Dizziness or feeling “off balance”	1.18±1.64 (0-5)	0.57±1.08 (0-5)
Tinnitus	2±1.82 (0-5)	1.07±1.48 (0-5)
<b>LIFESTYLE AND WORK IMPACT</b>		
How often are you affected by the mentioned elements?	2.59±1.72 (0-5)	0.90±1.46 (0-5)
How often does it affect you to take a shower?	3.04±1.55 (0-5)	0.98±1.56 (0-5)
<b>EFFECT ON HEALTH SYSTEM</b>		
How often do you consult a physician for your ear problems?	2.12±1.41 (0-5)	0.68±1.05 (0-4)
How often do you take medication for your ear discharge?	2.12±1.58 (0-5)	0.43±0.93 (0-4)
<b>GENERAL</b>		
What is the effect of your ear problems in your life?	3.46±1.45 (0-5)	1.22±1.49 (0-5)
<b>TOTAL POINTS</b>	27.65±12.11 (5-58)	9.66±8.68 (0-32)

\*Data given as mean±sd (standard deviation) (min-max).

**Figure 1.** Mean scores obtained from the preoperative and postoperative COMQ-12 questionnaires.

## Discussion

Evaluation of chronic otitis media results has been limited to the evaluation of recurrence rates and hearing assessment outcomes. The results do

not generally reflect patients' view of their improvement and its effect on their life. However, using a patient-based overview measures the impact of the disease and treatment from the patient's point of view rather than the clinician<sup>10</sup>.

**Table I.** Comparison of COMQ-12 sub-dimension and total scores; pre and postoperatively.

COMQ-12	Pre-op	Post-op	<i>p</i> *
Symptom severity	12 (3-34)	4 (0-19)	<i>p</i> <0.001
Lifestyle and work impact	5 (0-10)	1 (0-10)	<i>p</i> <0.001
Health service impact	4 (0-10)	0 (0-7)	<i>p</i> <0.001
General discomfort	4 (0-5)	1 (0-5)	<i>p</i> <0.001
Total score	25 (5-58)	7 (0-32)	<i>p</i> <0.001

\**p*-values are from the Wilcoxon test. Expressed data as median (min-max).

**Table II.** Comparison COMQ-12 survey results according to surgical success.

COMQ-12	Perforated	Intact	<i>p</i> *
<b>Post-Operative</b>			
Symptom severity	3 (0-13)	5 (0-19)	<b>0.137</b>
Lifestyle and work impact	5 (0-6)	1 (0-10)	<b>0.797</b>
Health service impact	0 (0-69)	0 (0-7)	<b>0.207</b>
General discomfort	1 (0-5)	1 (0-5)	<b>0.914</b>
Total score	6 (0-21)	7.50 (0-32)	<b>0.246</b>

\**p*-values are from the Wilcoxon test. Expressed data as median (min-max).

COMQ-12 questionnaire was developed to assess the severity of the disease from the patient's point. It has been translated into many languages and is known to be a valid, reliable, and sensitive implement to show COM patients' quality of life<sup>11</sup>. Both COMQ-5 and COMQ-12 were assumed to contain "somatic", "psychological," and "social" domains outlined by Koller and Lorenz<sup>12</sup>.

In this study, 83 (85%) of the patients had intact tympanic membranes at the postoperative 12<sup>th</sup> month. This graft uptake ratio was similar to the outcomes of the recent studies<sup>4,13,14</sup>. The mean change in preoperative and postoperative air conduction values was 8.78 (SD 1.17), and the mean change in preoperative and postoperative ABG values was 7 (SD 0.8); both showing statistical significance with current literature<sup>15,16</sup>.

According to the COMQ-12 questionnaire data at the 12<sup>th</sup> month after surgery, patients' symptom complaints, negative effects on daily life and work routine, on health care, and general well-being were significantly reduced compared to the preoperative period. These results, similar to the literature, imply a change in the quality of life in the postoperative period<sup>1,4,17</sup>. We found that many of our patients had excellent graft uptake and hearing gain results, whereas some were faced with complications such as graft uptake failure and insufficient hearing gain. There was no statistically significant difference when we compared COMQ-12 survey results according to surgical success. Patients still had fewer complaints or discomfort postoperatively, likely with a similar study<sup>17</sup>. COMQ-12 scores were unexpectedly lower, as the results reported in literature<sup>1,18,19</sup>. Although we thought the surgery had failed, most of the perforation sizes were observed to be smaller, and patients did not complain of any pain or ear discharge which might be due to the eradication of infection during the operation.

The limitations of this study were the short follow-up time, being a single-center study, and the relatively low volume of patients.

## Conclusions

Type 1 tympanoplasty creates a remarkable improvement in the quality of life of patients postoperatively. We believe that focusing only on the objective improvements such as graft uptake success or hearing gain alone should not be the only aim while treating our patients. Caring about subjective improvements is much more important in meeting our patients' expectations and increasing their quality of life.

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## Authors' Contributions

In this study, Melis Demirag Evman and Tolga Cakil equally contributed to the conception and design of the study, acquisition of data, analysis, and interpretation of data; drafting the article and making critical revisions related to relevant intellectual content of the manuscript; supervision; validation and final approval of the version of the article to be published.

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## Conflict of Interest

The authors declare that they have no conflict of interest to declare.

### Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request. All data generated or analyzed during this study are included in this published article.

### Informed Consent

All participants gave their informed consent.

### Ethics Approval

The ethics approval was obtained by the Kartal Dr. Lutfi Kirdar Training and Research Hospital Ethics Committee (approval number 2022/514/223/4).

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