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The DILATE Study: A Prospective Cohort Study of Balloon Dilatation for Eustachian Tube Dysfunction in patients with no middle ear disease.

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Abstract

Objective: This study evaluates the safety and utility of eustachian tube balloon dilatation (ETBD) in treating eustachian tube dysfunction (ETD) symptoms in adults without middle ear disease.

Methods: A prospective cohort study was performed. Adults with dilatory ETD symptoms and no middle ear disease underwent ETBD. A clinical assessment including tympanometry, pure tone audiometry, otoscopy, ability to Valsalva, and a Eustachian Tube Dysfunction Questionnaire (ETDQ-7) was performed pre-operatively and repeated during a 12 month follow-up period.

Results: Fifteen participants were enrolled. The mean pre-operative ETDQ-7 score of 4.6 reduced to 2.5 at six weeks ($P < 0.01$), 3.0 at six months ($P = 0.02$) and 2.6 at 12 months ($P < 0.01$) post-operatively. All patients without evidence of negative middle ear pressure had ETDQ-7 score improvements. There were no post-operative complications.

Conclusion: ETBD is safe and effective at treating ETD in patients with no middle ear disease or evidence of negative middle ear pressure.

MeSH Keywords: sensorineural hearing, tinnitus, inner ear, otology, otitis media.

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Introduction

Eustachian tube dysfunction (ETD) is a disabling and difficult to treat condition. It is estimated to have a prevalence of one to five percent in the adult population and contributes to a significant healthcare visit burden.[1–3] ETD occurs in the setting of inadequate middle ear ventilation and it may contribute to diseases of the middle ear such as otitis media and cholesteatoma.[4, 5] Patients typically present with symptoms such as otalgia, ear fullness, tinnitus, popping and muffled hearing.[4]

A number of surgical and non-surgical treatments are available for ETD. Evidence for the efficacy of non-surgical interventions such as intranasal corticosteroids, topical decongestants and mechanical pressure equalisation devices is scarce.[6, 7] Surgical techniques such as myringotomy with tympanostomy tube insertion improve middle ear ventilation, however, it may lead to complications such as tympanosclerosis and chronic perforation.[8] Eustachian tube balloon dilatation (ETBD) is a novel endoscopic procedure that dilates the cartilaginous portion of the eustachian tube. This technique improves middle ear ventilation by increasing eustachian tube compliance and inducing histopathological changes.[8, 9] Several studies have demonstrated the efficacy of ETBD in treating ETD.[8, 10, 11]

A recently published set of consensus statements by the American Academy of Otolaryngology-Head and Neck Surgery stated that "patient-reported symptom scores alone are insufficient to establish a diagnosis of obstructive ETD".[12] Similarly, a European consensus statement concluded that the diagnosis of dilatory (obstructive) ETD requires patient-reported symptoms in addition to tympanic membrane retraction or a

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tympanogram indicating negative middle ear pressure.[4] However, it is possible for patients with normal tympanometry and otoscopy to experience ETD symptoms, especially if their abnormal tympanometry may not be documented at the time of clinical assessment.[6, 13 – 15]

Patients enrolled in studies evaluating ETBD often had concurrent middle ear disease.[8, 10, 11] It is unclear what effect the pre-operative middle ear may have on the efficacy of ETBD in reducing ETD symptoms. As a result, the patient population that may benefit from the procedure remains poorly defined. Furthermore, there has been no prospective analysis of ETBD in an Australian population. This study was developed to better understand the utility of ETBD at treating dilatory ETD symptoms in patients without middle ear disease.

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Materials and Methods

Patients

A prospective cohort study was conducted. It included patients undergoing ETBD at two centres over a two-year period. Patients were recruited at a pre-operative assessment and evaluated by two Otolaryngologists (authors JK and SL). Patients were invited to participate based on a set of inclusion and exclusion criteria (Table 1). Informed consent was taken from all individual participants. Each patient was given study information and advised they could withdraw from the study at any time.

Ethics

This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and approved by an institutional Human Research and Ethics Committee (HREC registration number 1805). Data were collected by a single investigator, stored on a secure network, and de-identified once entered into the study database.

Pre- and post-operative assessments

Participation involved a routine pre-operative assessment before ETBD. This included clinical history, examination (otoscopy and Valsalva test), tympanometry, pure-tone-audiometry (PTA), completion of a Eustachian Tube Dysfunction Questionnaire (ETDQ-7) and computerised tomography imaging of the temporal bones (CTTB). The seven-item ETDQ-7 was developed in 2012 as a tool for ETD symptom assessment. It provides a valid and reliable technique by which symptom severity can be assessed and improvement post-treatment quantified.[16] Clinical history was used to categorise ETD symptoms as acute (<3 months) or chronic (>3 months).[4]

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Medical charts were reviewed to collect descriptive data of participants. Data were collected and analysed from routine follow-up at fixed intervals of six weeks, six months, and twelve months post-ETBD. This included the results of repeat assessments post-procedure with clinical history, examination (otoscopy and Valsalva test), tympanometry, PTA and completion of ETDQ-7. Statistical analyses were performed using R commander 4.2.3 and statistical significance was defined as $P < 0.05$. All reported P-values were calculated using a two-tailed independent sample t-test.

Surgical technique

All ETBD procedures were performed by a single surgeon (SL) using a general anaesthetic. An endoscopic approach with a zero-degree rigid scope was used to introduce an XprESS ENT Dilation System (Entellus Medical) device. The 20mm long dilatation device was inserted into the cartilaginous portion of the eustachian tube at an approximate 45-degree angle (Figure 1). Using the Seldinger technique, a balloon was inserted over the device and inflated with sterile water to 12 atm for two minutes.

Aims

The primary aim of this study was to prospectively evaluate the impact of ETBD in patients without middle ear disease, using clinical examination (status of tympanic membrane and ability to Valsalva), PTA, tympanometry and ETDQ-7 scores at six weeks, six months and twelve months post-procedure. The secondary aim was to investigate the presence of any post-operative complications following ETBD.

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Results and analysis

Fifteen participants were included. All patients attended the post-operative six-week follow-up, nine (60.0%) the six-month follow-up and fourteen (93.3%) the 12-month follow-up. Ten patients (66.7%) were female, and the mean age was 56 years (range: 29 – 78 years).

The pre-operative characteristics of each study participant is described in Table 2. Thirteen (86.7%) participants presented with symptoms of chronic ETD, and two (13.3%) with acute ETD. All patients had a normal tympanic membrane and no middle ear effusion. A pre-operative CTTB confirmed the absence of middle ear and mastoid pathology in each patient. Two participants had radiographic evidence of mild sinonasal disease in the absence of sinonasal symptoms. Both were deemed eligible for inclusion given a lack of clinical evidence for active sinonasal disease. Seven patients had left ear ETD, two had right ear ETD and six had bilateral ETD. Of the 21 balloon dilatations performed, no intra-operative or immediate post-operative complications were noted. Pre-operatively, fourteen (93.3%) patients had type A tympanometry, and one (6.7%) had type C. Four (26.7%) participants were unable to Valsalva and four (26.7%) had sensorineural hearing loss (SNHL) prior to surgery.

The mean pre-procedure ETDQ-7 score was 4.6 (range: 3.4 – 6.3), indicative of patient assigned moderate to severe symptoms. The mean post-procedure ETDQ-7 scores were 2.5 (range 1.1 – 4.3), 3.0 (range 1 – 5.9) and 2.6 (range 1.3 – 4.7) at six weeks, six months, and 12 months follow-up, respectively (Figure 2). Improvements in mean post-operative ETDQ-7 scores were statistically significant in comparison to pre-operative scores (Table 3). There was no significant difference between mean post-operative ETDQ-7 scores. All fourteen

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patients presenting with type A tympanometry demonstrated statistically significant improvements in ETDQ-7 scores six weeks ($P < 0.01$), six months ($P = 0.042$) and 12 months ($P < 0.01$) post-operatively, in comparison to pre-treatment scores.

Of the patients attending follow-up, fourteen (93.3%) at six weeks, eight (88.9%) at six months and fourteen (100%) at 12 months had improvements in total and mean ETDQ-7 scores pre- and post-operatively (Figure 3). One third of participants sustained a 50% improvement in ETDQ-7 scores 12 months post-operatively. Patients with an ETDQ-7 score improvement of at least 50% at 12 months had higher mean pre-operative scores than cases with less than 50% improvement (5.4 versus 4.3, $P = 0.03$, 95% CI: 0.1 – 2.1).

No patient had an abnormal otoscopic examination post-operatively. All four (26.7%) patients that failed to Valsalva pre-treatment were able to do so six weeks following ETBD. At the time of their last follow-up, three of four patients maintained the ability to Valsalva. (Table 4). Type C tympanometry of a single (6.7%) patient remained unchanged pre- and post-operatively. Another patient, with pre-procedure type A tympanometry, developed concurrent cochlear hydrops and had type B tympanometry 12 months post-ETBD. All four patients with pre-operative SNHL had sustained SNHL at their last follow-up assessment. The PTA results for two of these patients were likely confounded by other pathology present at follow-up, including inner ear hydrops and upper respiratory tract infection (Table 5). No post-operative complications were noted in the 12 months following ETBD.

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Discussion

Over the last decade, balloon dilatation of the eustachian tube has emerged as a promising treatment for ETD. The safety and utility of the procedure continues to be an area of active research. ETBD devices were approved by the Australian Department of Health in 2016. To our knowledge, since approval, no prospective study has analysed the use of ETBD in an Australian population. This study's results demonstrate significant improvements in the ETDQ-7 scores of patients with normal middle ears, for at least 12 months following ETBD. The rate and extent of score improvement was similar to other publications.[8, 10, 11] Our results highlight the utility of ETBD in treating symptomatic patients that do not have objective evidence of negative middle ear pressure, and therefore do not strictly meet dilatory ETD diagnostic criteria.[4, 12] This study also demonstrates the strong post-operative safety profile of ETBD, which is consistent with current literature.[8, 10, 14, 15]

The pre-operative middle ear may influence ETDQ-7 scores following ETBD. A retrospective review of 62 patients by Cheng et al., assessed ETDQ-7 scores six months to two years following ETBD.[17] The authors demonstrated that 83.9 to 100% of patients without middle ear disease had improvements in scores pre- and post-ETBD. These figures are similar to our data. Additionally, Cheng et al., found that a subgroup of patients with middle ear pathology had inferior improvements in ETDQ-7 scores.[17] These preliminary findings may suggest that middle ear disease can reduce the extent of symptom improvement post-ETBD. However, other studies have demonstrated that the presence of middle ear pathology, such as chronic otitis media, independently predicts a greater likelihood of ETDQ-7 score normalisation (ETDQ-7 score < 2.1) following ETBD.[18] Limited studies have compared outcomes of ETBD in those with and without middle ear disease. Further research is warranted to better

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understand predictors of symptom improvement and the effect of middle ear status on post-operative ETDQ-7 scores.

No patients in our study had tympanic membrane retraction and one (6.7%) had a sustained type C tympanogram, pre- and post-ETBD. The remaining 93.3% of participants, with no objective evidence of negative middle ear pressure, all had statistically significant improvements in ETDQ-7 scores post-operatively. These findings are consistent with current studies, and underline the idea that symptomatic dilatory ETD can be treated with balloon dilatation, regardless of normal tympanometry or otoscopic examination.[13] Using conventional interpretation where type A tympanograms are -100 to +25 daPa, type B have no peak pressure and type C are less than -100 daPa, tympanometry may lead to underdiagnosis of ETD.[19] Additionally, the test may be unreliable when used to monitor the efficacy of ETBD or identify patients that may benefit from the procedure.[11, 14, 18 – 21] Although our data suggest ETBD may be performed on the sole basis of subjective measures, caution must be taken as this approach could greatly expand the number of surgical candidates. It is likely that a combination of subjective and objective measures are optimal to determine eligibility for ETBD and ongoing assessment of disease progression.

Several balloon catheter devices exist for dilatation of the eustachian tube. These include the XprESS ENT Dilation System (Entellus Medical), the Bielefield system (Spiggle and Theis) and the Aera balloon catheter (Acclarent). Variations exist amongst devices and surgical techniques, such as balloon sizes, inflation pressures, duration of inflation and the angle of catheter insertion.[8, 11, 22] For example, a prospective analysis of ETBD by Poe et al., used a shorter catheter (16mm vs 18mm) and inflated the device for less time (1 minute vs 2

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minutes) in comparison to our approach.[23] The subtle differences in operative techniques and device characteristics may play a significant role when evaluating ETBD efficacy, however, this role is yet to be studied. Current literature emphasises that care must be taken to avoid catheter advancement into the bony eustachian tube, in order to minimise the risk of carotid artery injury on balloon inflation.[24] In our study, the dilation device was bent at the 20mm mark for eustachian tube access, preventing overly deep catheter insertion. Serious, albeit rare complications following ETBD have been reported in the literature, such as carotid artery dissection and stroke, surgical emphysema, and the development of patulous ETD.[25]

There are a number of limitations to this study. Given our small sample size and short-term follow-up, further research is warranted to investigate long-term ETBD outcomes in larger Australian cohorts. Our post-operative data must be interpreted with caution as the ETDQ-7 solely relies on subjective measures, which are difficult to validate against objective post-ETBD tests. The development of inner ear hydrops and upper respiratory tract infection in patients during the follow-up period likely confounded the interpretation of PTA results. Additionally, patients were free to use medical interventions (such as intranasal corticosteroids) following ETBD. Although these interventions have a limited role in ETD management, this may have confounded study data.[6, 7] Nevertheless, this study's prospective design had the advantage of longitudinally tracking changes in each patient's subjective and objective measures post-operatively.

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Conclusion

For the first year post-operatively, ETBD may be a safe and effective procedure to treat dilatory ETD symptoms in patients without middle ear disease. Although a strict diagnosis of dilatory ETD requires objective evidence of negative middle ear pressures, ETBD may improve subjective symptom control in patients with normal tympanometry and otoscopic examination.[4, 12]

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Competing Interests

The authors declare none.

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Summary

- Eustachian tube balloon dilatation (ETBD) is a novel treatment for eustachian tube dysfunction (ETD). Studies evaluating the efficacy of ETBD often enrol patients with concurrent middle ear disease.
- Recently published consensus statements have concluded that the diagnosis of ETD requires patient-reported symptoms along with objective evidence of negative middle ear pressure.
- This prospective study enrolled patients with symptoms of dilatory ETD in the absence of middle ear disease. The data demonstrates the efficacy of ETBD in improving subjective ETD symptoms in patients without middle ear disease.
- Findings demonstrate that patients who did not meet diagnostic criteria for ETD, due to the lack of evidence for negative middle ear pressures, still benefited from ETBD.

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Table 1. Inclusion and exclusion criteria for enrolment of study participants.

Inclusion Criteria
1. Age 18 years or older
2. Clinical diagnosis of dilatory ETD, with at least one symptom on the Eustachian Tube Dysfunction Questionnaire
3. Failed medical management of ETD
Exclusion Criteria
1. Previous head and neck radiation treatment
2. Post-nasal space tumours
3. Ossicular erosion
4. Active paranasal sinus disease
5. Active middle ear disease (tympanic membrane perforation, acute otitis media, chronic suppurative otitis media, cholesteatoma)
6. Carotid artery dehiscence on CTTB imaging
7. Inner ear hydrops or Ménière's disease on CTTB imaging
8. Temporomandibular joint disorder on CTTB imaging

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Table 2. Pre-operative characteristics of study participants.

Patients	Symptom Timeframe	Affected Ear	Otoscope Examination	Able to Valsalva	Tympanometry	Pure Tone Audiometry
Patient 1	Chronic	Right	Normal	Yes	Type A	Normal
Patient 2	Acute	Left	Normal	Yes	Type A	SNHL
Patient 3	Acute	Right	Normal	No	Type A	Normal
Patient 4	Chronic	Bilateral	Normal	Yes	Type A	SNHL
Patient 5	Chronic	Bilateral	Normal	Yes	Type A	SNHL
Patient 6	Chronic	Left	Normal	Yes	Type A	Normal
Patient 7	Chronic	Left	Normal	Yes	Type C	Normal
Patient 8	Chronic	Left	Normal	Yes	Type A	Normal
Patient 9	Chronic	Bilateral	Normal	No	Type A	SNHL
Patient 10	Chronic	Left	Normal	No	Type A	Normal
Patient 11	Chronic	Bilateral	Normal	Yes	Type A	Normal
Patient 12	Chronic	Bilateral	Normal	Yes	Type A	Normal
Patient 13	Chronic	Bilateral	Normal	Yes	Type A	Normal
Patient 14	Chronic	Left	Normal	No	Type A	Normal
Patient 15	Acute	Left	Normal	Yes	Type A	Normal

Abbreviations: SNHL – sensorineural hearing loss.

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Table 3. Statistical significance of mean ETDQ scores pre-operatively and six weeks, six months, and 12 months post-ETBD.

	Six weeks	**Six months**	**12 months**
Pre-ETBD	P = 0.000003 * (95% CI: 1.4 – 2.9)	P = 0.02 * (95% CI: 0.3 – 2.9)	P = 0.000007 * (95% CI: 1.3 – 2.8)
Six weeks		P = 0.37 (95% CI: -1.9 – 0.8)	P = 0.76 (95% CI: -0.9 – 0.7)
Six months			P = 0.48 (95% CI: -0.9 – 1.8)

** Statistically significant, p<0.05*

Footnote: A two-tailed independent sample t-test was performed to calculate p-values and 95% confidence intervals.

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Table 4. Progression of patients unable to Valsalva pre-operatively at six weeks, six months, and 12 months post-ETBD.

Patients	**Pre-operatively**	**Six weeks**	**Six months**	**12 months**
Patient 3	No	Yes	DNA	DNA
Patient 9	No	Yes	Yes	No
Patient 10	No	Yes	Yes	Yes
Patient 14	No	Yes	DNA	Yes

Abbreviations: DNA – did not attend follow-up.

Footnote: No – unable to Valsalva. Yes – able to Valsalva.

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Table 5. Progression of abnormal pure tone audiometry (PTA) results pre-operatively and six weeks, six months, and 12 months post-ETBD.

Patients	**Pre-operative**	**Six weeks**	**Six Months**	**12 months**
Patient 2	SNHL	SNHL	DNA	-
Patient 4 †	SNHL	SNHL	SNHL	SNHL
Patient 5 ‡	SNHL	Normal	SNHL	SNHL
Patient 9	SNHL	SNHL	SNHL	-

Abbreviations: CHL – conductive hearing loss, SNHL – sensorineural hearing loss, DNA – did not attend follow-up.

† Had upper respiratory tract infection at 12 months follow-up.

‡ Developed inner ear hydrops at six months follow-up.

Footnote: Patient 2 and Patient 9 did not complete pure tone audiometry at 12 months.

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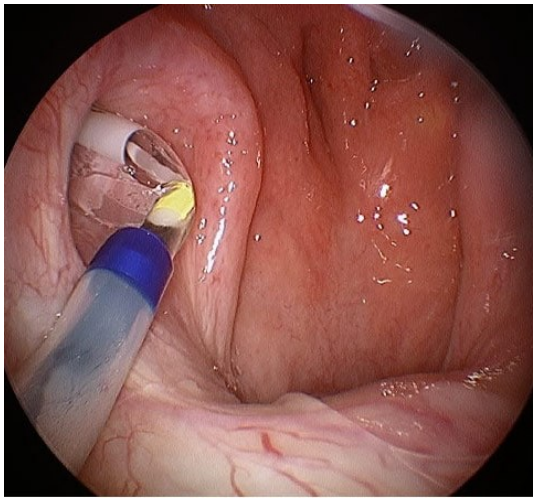

Figure 1. Endoscopic image of eustachian tube dilatation. The eustachian tube is approximately 35mm long and 3mm in diameter, with a 4:1 ratio of cartilaginous to bony length.

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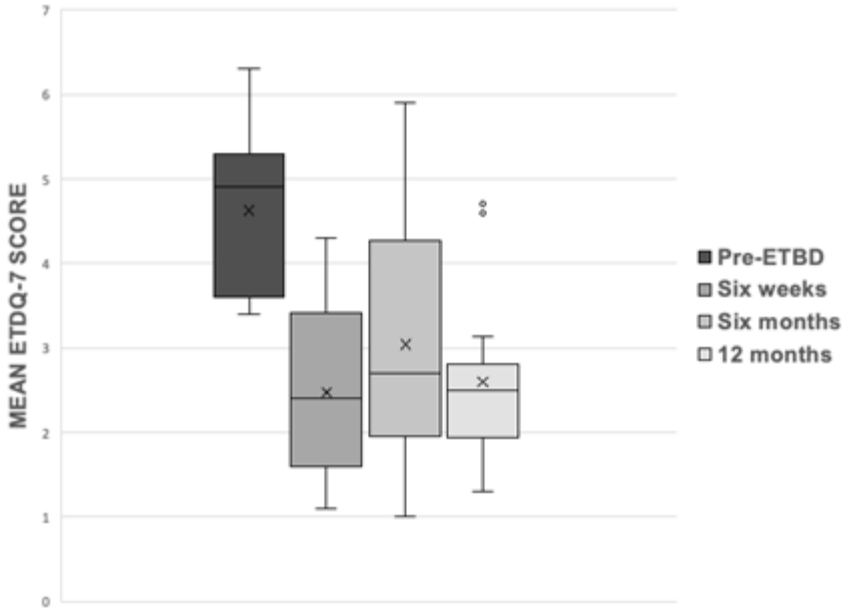

Figure 2. Patients' mean ETDQ-7 scores pre-ETBD and six weeks, six months, and 12 months post-procedure.

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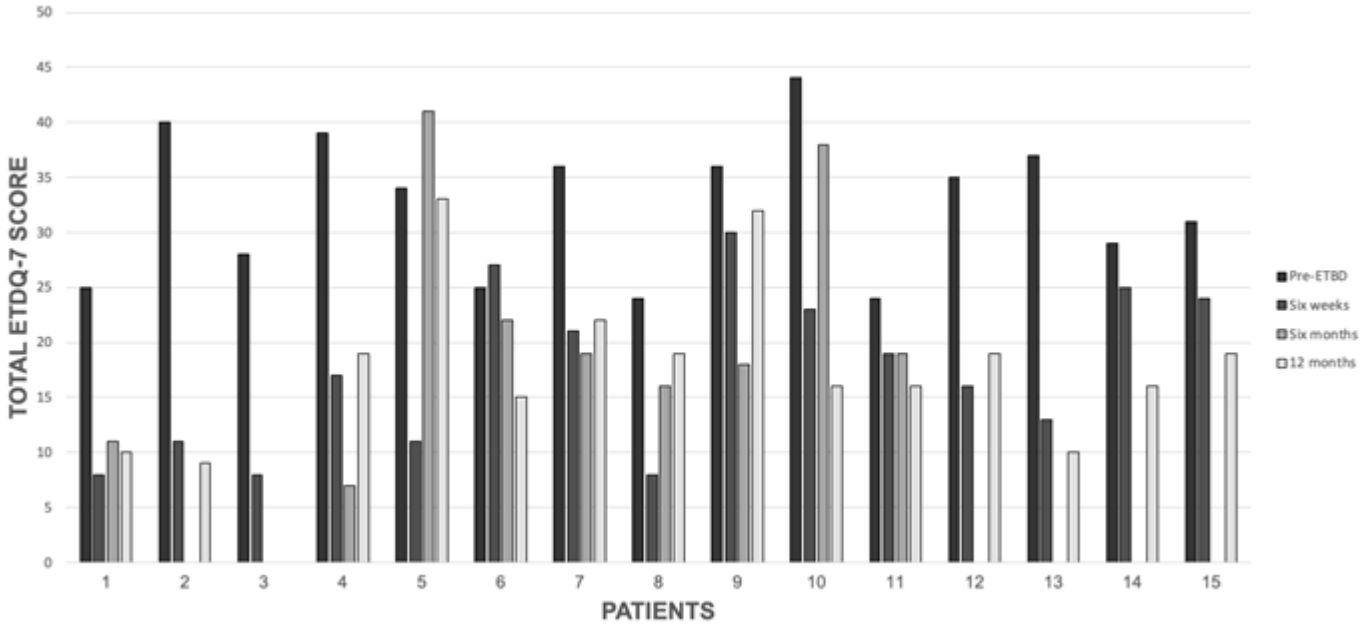

Figure 3. Patients' total ETDQ-7 scores pre-ETBD and six weeks, six months, and 12 months post- procedure.

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