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Original Article

Investigation of Eustachian Tube Dysfunction by Tubomanometry in Patients Undergoing Tympanoplasty for Chronic Otitis Media

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BACKGROUND: The eustachian tube is an anatomical structure that connects the nose, nasopharynx, middle ear, and mastoid air cells and has important functions. If the physiological functions of the eustachian tube are impaired, ear diseases may occur. There are many test methods used to evaluate the functions of the eustachian tube. However, none of these methods are accepted as the gold standard due to both the application difficulties of these methods and the reliability of their results. We aim to use tubomanometry for the detection of eustachian tube dysfunction (ETD) and so to increase the success rates of ear surgeries in patients diagnosed with tubal dysfunction with easily applicable methods.

METHODS: In this prospective study, the tubomanometry results of 34 patients diagnosed with chronic otitis media who underwent tympanoplasty were compared with 34 healthy controls. The tubomanometry measurements of patients diagnosed with chronic middle ear disease (affected ear side) and the control group (healthy ears) were compared.

RESULTS: A statistically significant increase in mean rising time was found between the control group and the patient group at first month postoperative, sixth month postoperative ($P < .01$). In the control group, eustachian function was found to be normal ($R < 1$) compared with that of the all patient groups ($P < .01$, first month postoperative comparison $P < .05$).

CONCLUSION: In the application of surgical methods used in the treatment of ETD, the ETD must first be determined with an objective test tool. According to the results of our study, one of the most objective tests that can be used in this regard is tubomanometry.

KEYWORDS: Tubomanometry, eustachian tube, dysfunction, chronic otitis media, tympanoplasty

INTRODUCTION

The eustachian tube (ET) is an anatomical structure that connects the nose, nasopharynx, middle ear, and mastoid air cells and has important functions. The ET has 3 main important functions: ventilation of the middle ear, drainage of middle ear fluids into the nasopharynx, and protection of the middle ear from nasopharyngeal secretions. If the physiological functions of the ET are impaired, ear diseases may occur such as acute otitis media, otitis media with effusion, chronic otitis media, tympanic membrane perforation, retraction pockets, adhesive otitis media, and secondary cholesteatoma.[1] There are many test methods used to evaluate the functions of the ET.[2] One of these is tubomanometry.

Tubomanometry was first described by Esteve in 2001.[3] The test records the pressure changes that occur through the nasal applicator (30, 40, and 50 mbar) during swallowing with a help of a probe inserted into the external auditory canal. The pressure changes are recorded via measurements of tympanic membrane movements, or in cases in which the tympanic membrane is ruptured, directly. The main purpose of tubomanometry is to measure the delay time between the delivery of pressure through the nose and the opening of the fibrocartilaginous part of the ET. Tubomanometry is used to induce the patient's swallowing reflex during the

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application of calibrated positive pressure to the nasopharynx. The fibrocartilaginous tube is opened with this high pressure and swallowing, and air passes from the nasopharynx to the middle ear. The device can automatically detect the initiation phase of swallowing and delivers air to the nasopharynx at a pressure of 300, 400, or 500 daPa. The opening of the ET can be measured from the external auditory canal.[4-6]

The main purpose of our study is to use tubomanometry, which is an easily applicable method for both patients and clinicians, but which is not yet a routine practice in Otolaryngology, and to increase the success rates of ear surgeries in patients diagnosed with tubal dysfunction with easily applicable methods such as balloon tuboplasty.

METHODS

This study was approved by the Eskişehir Osmangazi University Clinical Research Ethics Committee (approval number: 2016/12, date: January 11, 2016). All the patients signed informed consent forms prior to their inclusion in the study. In this prospective study, the tubomanometry results of 34 patients diagnosed with chronic otitis media who underwent tympanoplasty between 01.01.2017 and 31.12.2018 at Eskişehir Osmangazi University Faculty of Medicine, Department of Otorhinolaryngology were compared with 34 healthy controls. The control group had no complaints, and tympanometry values were normal. This comparison was designed to determine the rates of eustachian dysfunction and provide these patients the most effective treatment. The study was conducted with the patients who presented with ear complaints to the Eskişehir Osmangazi University Otorhinolaryngology Polyclinic. After anamnesis, an otolaryngological physical examination, temporal bone computed tomography, full audiological examination, and tympanogram were performed. After all these evaluations, patients with the following characteristics were included in the study: aged 18-65 years, scheduled to undergo a tympanoplasty due to chronic otitis media, and no discharge in their ears. The tubomanometry measurements of patients diagnosed with chronic middle ear disease (affected ear side) and the control group (healthy ears) were compared. The *R* values and P2-P1 values included in the tubomanometry results were collected for examination. These values were measured again at the 1-month and 6-month follow-ups after the operations were performed.

A tubomanometry device (Spiggle & Theis Medizintechnik, Germany-2015) and a computer program were used to measure and record the data (Figures 1 and 2). The tubomanometry device consists of an adjustable generator (capable of generating positive pressure in the range of 15-60 mbar), a synchronizing device (to detect the swallowing reflex and initiate pressure), a detector that detects pressure changes placed in the external auditory canal, a transducer (to measure pressure changes in the nose and rhinopharynx), an electronic processor that analyzes signals, and software that can print and record results. The device has a calibrated pressure generator and 2 high-sensitivity pressure detectors. One of these detectors is placed in the rhinopharynx, and the other is placed in the external auditory canal. The tubomanometry test can be performed in just a few minutes and does not cause any discomfort to the patient.

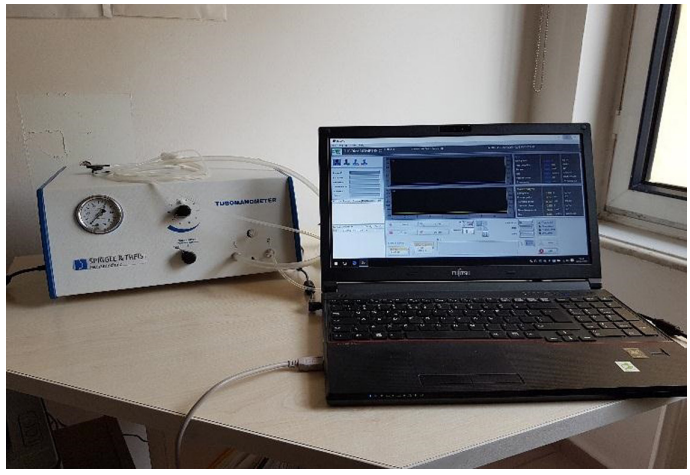

Figure 1. The "Tubomanometry device" and "computer" are where the data are recorded and evaluated.

First, the tubomanometry probes are placed in the patient's external auditory canal. The patient takes a sip of water in his mouth. Swallowing provides a strong reflex to open the ET. Two-armed adapter tips are placed in the patient's nose (Figures 3-5). The pressure generator and rhinopharynx pressure detectors are connected to the end of the adapter. Then the patient swallows the water with the mouth closed. With the swallowing motion, the device automatically detects the negative pressure in the rhinopharynx and begins to administer air pressure. With the opening of the ET, the air that passes into the middle ear is detected by the probes in the external ear canal. Because the test takes only a few minutes, it can be repeated easily on the same patient.

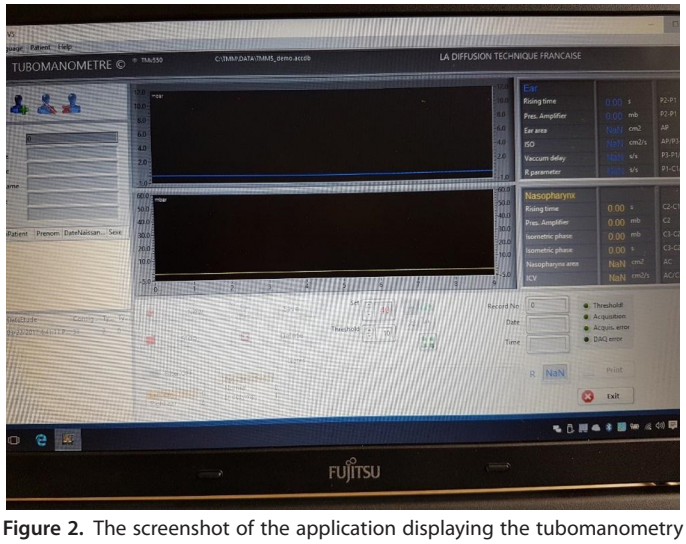

Figure 2. The screenshot of the application displaying the tubomanometry results.

MAIN POINTS

- In the application of surgical methods used in the treatment of ETD, the ETD must first be determined with an objective test tool.
- Although many tests are used in the diagnosis of ETD, none of them is a gold standard on its own.
- According to the results of our study, one of the most objective tests that can be used in this regard is tubomanometry.

Figure 3. The application of the tubomanometry ear probe.

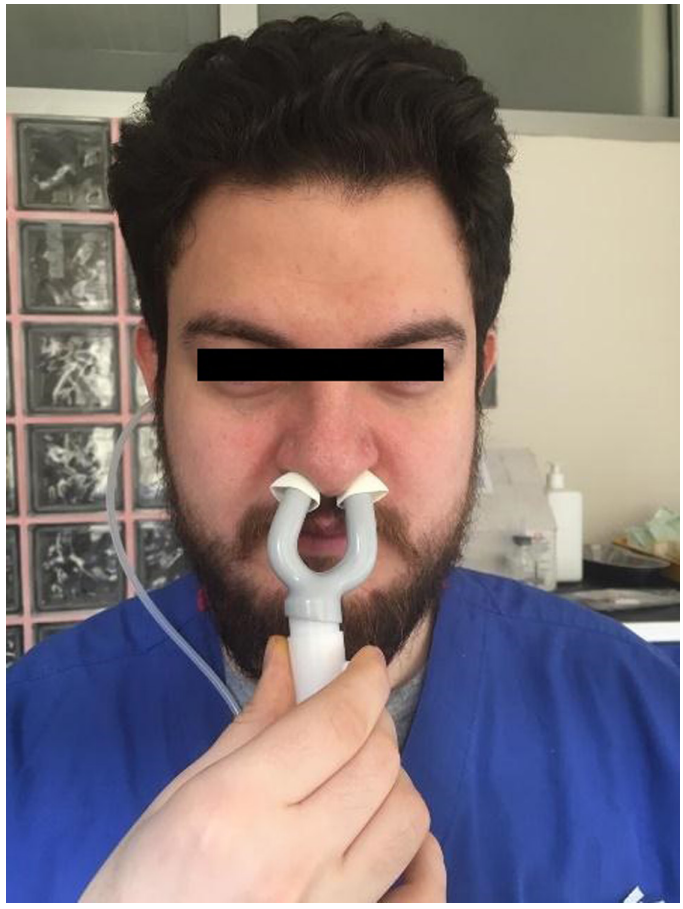

Figure 4. The application of the tubomanometry nasal probe.

An important parameter among the tubomanometry results is the latency between the pressure applied to the rhinopharynx and the opening of the ET. The opening of the ET can easily be measured from the external auditory canal with a rapid rise in the pressure curve (the upper curve in Figure 6). The pressure applied to the rhinopharynx can also be easily understood by the rhinopharynx pressure curve (the lower curve in Figure 6).

The Tubomanometric tests consist of 2 curves recorded from the rhinopharynx and the external auditory canal. The *X*-axis shows time, and the *Y*-axis shows the pressure value.

The lower curve in Figure 6 shows positive pressure in the rhinopharynx, which results in the opening of the fibrocartilaginous ET. The upper curve shows the pressure spreading from the tympanic membrane to the external auditory canal after the ET is opened. These curves (rhinopharynx), which are analyzed below, consist of 3 phases. The initial phase shows increased pressure in the nasal fossa and rhinopharynx with the closure of the soft palate. This curve shows the stimulus required to open the ET and for the onset of the swallowing reflex. C1 represents the start of the pressure increase in the nasopharynx, and C2 pinpoints the maximum pressure increase in the nasopharynx. If C2 is less than 10%, then the soft palate is not fully closed. The time from C1 to C2 is usually less than 0.3 seconds. The second phase shows a plateau in pressure. This curve, which is between C2 and C3, may differ even in the same patient. It also shows the isometric contractions in the soft palate. The third phase begins at C3 and shows a drop in pressure, which is related to the relaxation of the muscles in the palate and the release of air.

The upper curve in Figure 6 shows the pressure changes in the external auditory canal and the tympanic membrane movements after the opening of the ET. Pressure taken from an eardrum with a perforation or ventilation tube directly indicates intratympanic pressure. P1 represents the start of the movement of the eardrum. The P1-P2 phase indicates that the pressure in the middle ear increases with the lateral movement of the tympanic membrane. The P2-P3 phase is a horizontal line showing the maximum movement in the tympanic membrane. The time covered by this plateau is related to the duration of the pressure applied to the rhinopharynx. This means that the ET is open, and gas transfer occurs during this phase. The P3-P4 phase, which shows the evacuation of the middle ear, shows a drop in pressure in the tympanic cavity.

The opening latency index (*R*-value) reflects the latency between the pressure application in the epipharynx and the measurement of the pressure change in the ear canal. $R = $ P1-C1 (latency in the tubal opening) / C2-C1 (time taken to increase the pressure in the rhinopharynx) = 0.87 (standard value). This ratio shows the activity of both the soft palate and the ET. If $R < 1$, then the ET is opened before C2 (immediate opening/normal function). If $R > 1$, then it is opened after C2 (late opening/restricted function). If $R = \approx 0$, then the ET is patulous. Lack of opening (negative or measurable *R*) indicates complete obstruction of the ET.

The P2-P1 (seconds) value shows the duration of the lateral movement of the tympanic membrane, which is the time needed to balance the

Figure 5. The simultaneous application of the tubomanometry nasal and ear probes.

pressure in the middle ear with the opening of the ET. Its normal value is 0.9. Values less than 0.9 indicate a small mastoid cavity or hypertrophic mucosa. P2-P1 = 8.6 daPa is the normal value of the pressure change between the tube opening and pressure stabilization. This value does not change significantly with various pressure changes (30, 40, or 50 mbar). However, since the middle ear pressure directly reflects in the outer ear canal in perforated eardrums, P2-P1 shows high values with a steep curve. This indicates hypertrophic mucosa in the curves increasing as cadamellar. P3-P1 seconds/C3-P1 seconds = 1.41 is the ratio of the time the ET is open to swallowing time after the ET is opened[3,7]

Statistical Analysis

Data analysis was performed using IBM SPSS Statistics version 21.0 software (IBM SPSS Corp.; Armonk, NY, USA). Whether the distributions of continuous variables were normally distributed was determined using Shapiro–Wilk's test. Parametric tests were used in the analysis of normally distributed data, and non-parametric tests were used in the analysis of non-normally distributed data. The mean differences between 2 independent groups were compared using *t*-test (independent samples *t*-test) and Mann–Whitney *U* test. Two-way analysis of variance (ANOVA) test and Friedman test were used to evaluate pre-test and post-test data. Yates' chi-square test was used in the analysis of the created cross tables. McNemar test was used to compare before and after categorical data. Data are summarized as mean ± SD and median (Q1; Q3). $P < .05$ was considered statistically significant.

RESULTS

Of the 34 patients diagnosed with chronic otitis media who underwent tympanoplasty surgery in this study, 18 were males and 16 were females, and the mean age was 43.20 ± 10.4. The control group consisted of 34 patients who had no ear complaints and whose ears were evaluated naturally in ear, nose, throat (ENT) physical examination, 20 of them were males and 14 were females, and the mean age was 39.72 ± 12.01. The rising time (P2-P1 seconds) and *R* parameter values (P1-C1/C2-C1 seconds/seconds) were measured by tubomanometry.

The mean rising times (P2-P1 seconds) measured in the control group and at preoperative, first month postoperative, and sixth month postoperative in the patient group were 0.35 ± 0.04, 0.14 ± 0.04, 0.13 ± 0.06, and 0.17 ± 0.06 seconds, respectively.

A statistically significant increase in mean rising time was found between the control group and the patient group at first month postoperative, sixth month postoperative ($P < .01$).

When the mean rising times at preoperative and first month postoperative were compared with that at sixth month postoperative

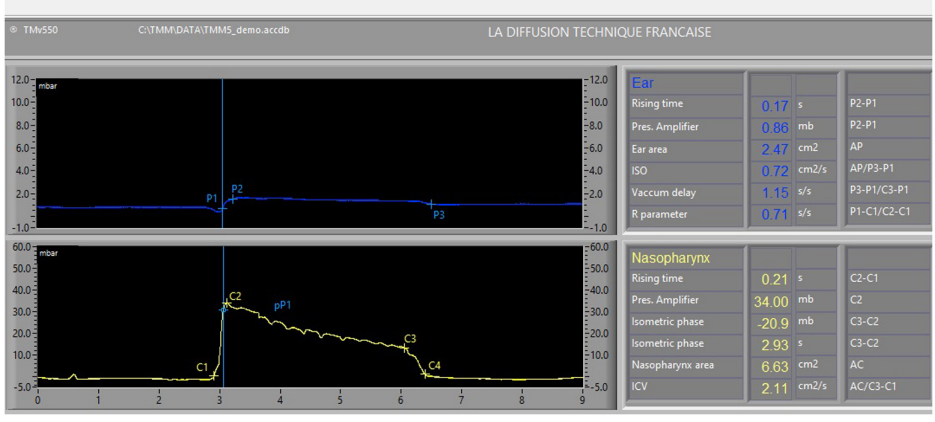

Figure 6. Tubomanometry test results.

respectively, a statistically significant difference was identified ($P = .03$, $P = .007$). By contrast, there was no difference between the preoperative and first month postoperative mean rising times ($P = 1.00$).

The median *R* parameter values (P1-C1/C2-C1 seconds/seconds) were calculated in the control group and at preoperative period, first month postoperative, sixth month postoperative in the patient group (Table 1). According to the Friedman test (non-parametric two-way ANOVA, Friedman's two-way ANOVA by ranks), there was no difference between the median *R* values at different times in the patient group ($P = .811$; $P > .05$). On the contrary, a statistically significant decrease was found between the median *R* values of the control group and the patient group at preoperative, first month postoperative, and sixth month postoperative ($P < .01$). According to their $R > 1$ and $R < 1$ values, the groups were evaluated within themselves in terms of eustachian dysfunction. There was no statistically significant difference between the preoperative, first month postoperative, and sixth month postoperative periods. In the control group, eustachian function was found to be normal ($R < 1$) compared with that of the all patient groups ($P < .01$, first month postoperative comparison $P < .05$). When the results of 6 patients in whom tympanoplasty operations were unsuccessful were examined, *R* was found to be >1 at all measurement times.

DISCUSSION

Eustachian tube dysfunction (ETD) is a common problem in otolaryngology practice. There is no consensus on the diagnostic criteria, and treatment is usually difficult. The symptoms of ETD include hearing loss, ear fullness, ear discharge, middle ear pressure imbalance, tinnitus, and vertigo. Abnormalities can be seen in the tympanogram and the eardrum. These symptoms may worsen or improve over time but are not pathogenomic for ETD. More severe symptoms include chronic otitis media with effusion, middle ear atelectasis, adhesive otitis, eardrum perforation, and cholesteatoma. Moreover, viral upper respiratory tract infection, chronic sinusitis, allergic sinusitis, adenoid hypertrophy, smoking, cleft palate, radiotherapy, decreased mastoid aeration, and NO_2 exposure play a role in the etiology of ETD.[8]

In a study on ETD, Smith and Tysome[5] listed a wide variety of test methods for evaluating ETD and emphasized the lack of a gold standard. The most accurate method is to use clinical tests, patient anamnesis, and tubomanometry values in combination. In particular, when tubomanometry was combined with Valsalva and Toynbee, sensitivity and specificity increased to 91% and 86%, respectively. When it was combined with tympanometry, its sensitivity and specificity became 96% and 96%, respectively.

The incidence of chronic otitis media increases in patients with ETD due to impaired middle ear ventilation.[1] Esteve[7] examined ETD rates in patients with chronic otitis media, 56 ears diagnosed with chronic otitis media, and 58 normal ears were examined. The ET was opened in 93% of the normal individuals; in 67%, it was opened in the early period, and in 26%, in the late period. In 51 of the patients with chronic otitis media, the ETs were open, and in 49%, it could not be opened at all. In the cases where the tube could be opened, 38% were opened late, and 13% were opened early. In this study, a statistically significant difference was found in the opening of the ET and the *R* indexes between the normal individuals and the patients. Particularly, the high percentage of late opening was very significant in terms of abnormal tube functions. Consistent with this study, the present paper found that ETD was statistically significantly higher in the chronic otitis media patients compared with the normal group.

Similar to previous works, the current study showed that delayed ET opening time or ET blockage is seen in chronic otitis media, and *R* index values are important in detecting tubal dysfunction.[4,7,9,10] These parameters cannot be easily returned to normal with tympanoplasty. Some authors have shown that eustachian functions improve with the creation of a healthy tympanic cavity with tympanoplasty.[11,12] However, such an outcome may not be achievable in a short time; no such data were obtained after the 6-month follow-up in the present study.

We found that there was a significant difference between the average values of rising time (P2-P1 seconds) and the *R* parameter (P1-C1/C2-C1; seconds/seconds) in the normal ear and the affected ear values, and these results remained the same 6 months after tympanoplasty was performed. We concluded that concurrent or preoperative tuboplasty would help increase the success rates of ear surgeries in patients diagnosed with tubal dysfunction with tubomanometry. All of our 6 patients who were found to have unsuccessful tympanoplasty results were found to have $R > 1$, and eustachian dysfunction was present in the patients. We believe that the data and averages obtained in our study are important in identifying patients who need to undergo tuboplasty. Therefore, we applied balloon tuboplasty to improve the results of our tympanoplasties and to verify this hypothesis. The results of this practice and our views on this subject will form the basis of our next study.

In the study conducted by Poe et al,[13] patients with chronic effusion and otitis media with tubal dysfunction were followed up for 2 years after diode laser tuboplasty. The achievement rates were 36% in the sixth month, 40% in the first year, and 38% in the second year. Jumah et al,[14] assesed the tubal openings of 30 patients in the preoperative and postoperative periods. These patients were followed up with a

Table 1. R Parameter Values

	Control	Preop.	Postop. First Month	Postop. Sixth Month
R parameter (P1-C1/C2-C1) sec/sec*				
Median	0.87 (0.19-1.52)	1.19 (0.31-2.21)	1.20 (0.65-2.12)	1.12 (0.30-2.20)
Interquartile range	0.55	0.60	0.49	0.55
$R < 1$ (normal) (%)	24 (70.6)	10 (29.4)	13 (38.2)	24 (70.6)
$R > 1$ (eustachian dysfunction) (%)	10 (29.4)	24 (70.6)	21 (61.8)	10 (29.4)

*Sec: second.

diagnosis of tubal dysfunction for at least 2 years. Tubal blockage was detected in 17 of the 30 patients in the preoperative period. In 13 (76%) of these 17 patients who underwent eustachian tuboplasty using diode laser, the tubal opening was protected in the fourth month postoperatively.

Tuboplasty is a recent intervention in the treatment of tubal dysfunction, which has an important effect on the formation of middle ear pathologies. Nonetheless, an objective tool, such as tubomanometry, is needed in the selection of patients requiring surgery. Tubal evaluation tests, except tubomanometry when used alone or in combination, have a success rate below 50% in evaluating ET functions. Hence, tuboplasty applications without tubomanometric evaluation are insufficient.[9,10,13,14]

Tubal functions can be correctly evaluated at rates over 95%, especially if tubomanometry, tympanogram, and ETDQ-7 results are interpreted together. This is crucial for patient evaluation and follow-up for tuboplasty. With further tubal evaluation experience gained from this study, we concluded that success in this area can be enhanced by applying combinations with other methods for tubal functions in the evaluation and follow-up of patients in the next stage. In addition, we have included a very valuable method in our clinical practice in order to contribute to the literature on this subject.

CONCLUSION

In the application of surgical methods used in the treatment of ETD, the ETD must first be determined with an objective test tool. According to the results of our study, one of the most useful tests that can be used in this regard is tubomanometry. In addition, we think that the treatment of ETD with surgical methods such as balloon tuboplasty will improve the results of chronic otitis media surgery. This idea will form the basis of our new study. We believe that new studies could be conducted with longer durations and a larger number of patients.

Availability of Data and Materials: The data that support the findings of this study are available on request from the corresponding author.

Ethics Committee Approval: This study was approved by the Ethics Committee of Eskişehir Osmangazi University (approval no.: 2016/12, Date: January 11, 2016).

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

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Declaration of Interests: The authors have no conflicts of interest to declare.

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