

Original Article

Broadband Sound Equalized by The Hearing Loss Curves as an Improved Stimulus for Tinnitus Retraining Therapy-A Pilot, Non-Controlled Observational Study

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OBJECTIVES: This study aimed to assess if a short tinnitus treatment, combining counseling with broadband noise filtered by the hearing loss curves, provided significant relief in tinnitus patients.

MATERIALS and METHODS: 25 tinnitus subjects of heterogeneous etiology were subjected to sound therapy, 1 hour per day, for 4 months. All of them underwent a unique initial counseling session aimed at undoing previous negative perceptions of tinnitus and highlighting the real expectations from tinnitus therapies. Customized stereo sound stimuli were designed by filtering broadband noise using the hearing loss curves of each ear. A monthly follow-up was carried out by assessing the severity of tinnitus through a validated Spanish version of the Tinnitus Handicap Inventory (THI).

RESULTS: 88% (22 of 25) of the patients completing the treatment obtained significant relief after 4 months. After 4 months of treatment, the average decrease in THI from its initial value for the 22 successful participants was 29.

CONCLUSION: The average THI score reduction after 4 months of treatment can be considered to be an excellent improvement when compared with other similar studies. The proposed customized sound therapy was effective in reducing tinnitus in patients of heterogeneous etiology.

KEYWORDS: Tinnitus, hearing loss, tinnitus retraining therapy

INTRODUCTION

Tinnitus is the conscious perception of sound in the absence of physical sound sources external or internal to the body^[1]. Epidemiological studies report that tinnitus affects roughly 10% of the adult population^[2], and severely disturbs the quality of life of about 1% of adults by producing anxiety, annoyance, irritability, stress, depression, and disturbed sleep patterns^[3,4]. For a current world population of around 7350 million, this amounts to more than 70 million tinnitus sufferers globally. This condition can be linked to several causes including: hearing disorders, aging, noise overexposure, ototoxic drugs, emotional stress, ear or head injuries, and neurological disorders.

Although the mechanisms causing tinnitus and hearing loss (HL) are not identical, the incidence of tinnitus is highly correlated with, and believed to be related to, HL. Since the prevalence of HL increases with age, the prevalence of tinnitus also increases with age^[5]. While not all individuals experiencing tinnitus have HL, subjects with HL have an 83% higher risk of developing tinnitus^[5].

Tinnitus is a very annoying condition, which is difficult to treat. A recent review evaluating 69 randomized clinical trials and comparing drug and non-drug treatments for subjective tinnitus, found that no treatment could be considered well established in terms of providing long-term reduction of tinnitus in excess of placebo effects^[6]. Although there is no effective drug for tinnitus at present, there are different therapies that can help cope with it. In many cases, tinnitus improves slowly over time by a process called habituation as the brain starts to adapt to tinnitus and pay less attention to it. When tinnitus sufferers reach habituation, they are no longer excessively

aware of it and do not find it so annoying. Habituation is the ultimate aim of most tinnitus therapies. Although many different treatments have been proposed, the most successful one has been the tinnitus retraining therapy (TRT), which is based on Jastreboff's neurophysiological model^[7, 8]. Tinnitus retraining therapy consists of counseling, which aims to reclassify tinnitus into the category of neutral stimuli, and sound therapy, which intends to decrease the strength of tinnitus-related neuronal activity^[8]. Tinnitus retraining therapy does not attempt to suppress the tinnitus source or to directly attenuate tinnitus-evoked reactions, but to prevent the tinnitus signal from reaching the brain, thus suppressing its negative reactions^[8].

In the TRT proposed by Jastreboff, sound stimulus consisted of broadband noise covering the entire audible frequency range. However, many other sound stimuli have been tried during the past decades^[9], including narrowband noise^[10], natural sounds^[11], oddball sequences^[12], sequences of tone pips or tone bursts^[13], a coordinated reset sequence of tone bursts of different frequencies one octave around the tinnitus pitch^[14], notched music^[15], and sequences of tone bursts with precisely timed, mild electrical pulses delivered to the cheek or neck^[16]. Some of these stimuli are not personalized for patients, while others are matched either to their HL or to their tinnitus pitch. However, Schaette and Kempster^[17], demonstrated that, if tinnitus had developed due to homeostatic plasticity after HL, stimulating the auditory system with a matched noise (a noise with the same spectrum as that of the HL curve) could reverse the increase of firing rate and gain induced by tinnitus.

Standard TRT protocol requires that patients listen to the designed sound stimuli for a few hours each day for at least 12 months^[8]. However, most patients find significant improvement 3-4 months after treatment initiation^[8]. Usually the sound stimuli are delivered via sound generators or hearing aids at a comfortable level slightly below the tinnitus level. Unpleasant sounds or impatience of the subjects to adhere to the sound therapy pattern may decrease treatment compliance. Therefore, easing sound delivery and decreasing the treatment period could help increase treatment compliance. The main aim of this work was to assess if a short TRT treatment, comprising counseling combined with broadband noise filtered with an HL filter and delivered through a smartphone connected to earphones, could provide significant relief to tinnitus patients.

MATERIALS AND METHODS

This research is presented according to the STROBE (STrengthening the Reporting of OBServational studies in Epidemiology) statement^[18].

MAIN POINTS

- 25 tinnitus patients are subjected to improved sound stimuli consisting of stereo broadband noise filtered by the hearing loss curves of both ears.
- These customized broadband stimuli were played using a smartphone with good quality headphones one hour per day for 4 months.
- When these sound stimuli are combined with an initial counseling session, 88% of patients decrease their THI 28 points in average.

Participants

Figure 1 shows the flow diagram of participants. 57 subjects were initially recruited for the treatment. Fifteen of them were excluded because they did not fulfill the inclusion criteria. For inclusion, subjects had to be aged between 18 and 70 years, have a Tinnitus Handicap Inventory (THI) score of more than 25, and agree to participate in the study for a period of 4 months. Participants with objective tinnitus, a history of psychiatric disorders, presence of Menière disease, or using hearing aids, were excluded from the study. 17 of the 42 elected subjects left the treatment before completion. A total of 25 tinnitus sufferers, complying with the selection criteria and recruited between January 2018 and July 2019 from different cities in Spain, completed the treatment. Ten of them were women (45±8 years) and 15 were men (52±10 years). All the participants had previously visited other specialized tinnitus clinics or otorhinolaryngologist specialists. Thus, they had already received some treatment (pharmacological, sound therapies) without significant improvement.

This study was carried out in accordance with the ethical standards laid out in the 1964 Declaration of Helsinki and was approved by the Institutional Ethical Committee of the CSIC. Informed consent was obtained from all individuals included in this study.

Patient Assessment

Participants underwent audiological and tinnitus assessment, and their clinical history was recorded. Audiological assessment consisted of HL assessment for both ears by pure-tone audiometry from 125 Hz to 8 kHz using the clinical audiometer GS61 (Grason-Stadler Inc., Madison, WI, USA). Figure 2 shows the mean HL curves of both ears of the 25 participants who completed the treatment. Average HL curves display hearing losses at frequencies higher than 2 kHz for both ears.

The tinnitus characteristics were assessed on the basis of the responses of the participants to the clinical evaluation sheet. The interview of the participants included temporal (variability), spectral (pitch), and spatial (location) aspects of their tinnitus. Furthermore, additional information about the participants, including anamnesis (clinical history) and tinnitus severity by means of a Spanish version of the Tinnitus Handicap Inventory (THI)^[19] was obtained. The anamnesis gathered information about the history and descriptive characteristics of the tinnitus, their possible etiology, previous tinnitus treatments, and relevant comorbidities.

The type and pitch of the tinnitus were evaluated using a custom-designed Graphical User Interface (GUI). Using this GUI, tones and ringing and hissing sounds can be easily created. The sounds were generated by passing noise through a band-pass filter. Two parameters, central frequency and bandwidth, determine the type of sound. The bandwidth is defined as a percentage of the central frequency at half-peak value. For instance, for tones the bandwidth is very narrow (0.1%). Ringing sounds are narrowband noises (bandwidth less than 10%) while hissing sounds are wideband noises (bandwidth greater than 10%).

Table 1 summarizes the assessed tinnitus characteristics of the 25 participants. Most patients had a tinnitus duration (fourth column) of less than 2 years (24 months), though some had longer durations (9 patients). Concerning the tinnitus laterality, 14/25 (56%) patients located their tin-

Table 1. Tinnitus characteristics of participants

Subject	Sex	Age	Tinnitus duration (months)	Tinnitus location	Tinnitus sound	Tinnitus pitch (Hz)	Tinnitus bandwidth (%)	Tinnitus etiology	THI (Initial)	DTHI
1	F	45	4	Bilateral	Hissing	2000	50	HL induced	56	-44
2	M	42	24	Right ear	Ringling	8000	10	Stapectomy	36	-22
3	M	37	14	Left ear	Ringling	7000	2	Eustachian tube dysfunction	26	-24
4	M	69	10	Left ear	Hissing	3500	20	Stress. Noise induced	48	-18
5	F	29	3	Bilateral	Hissing	3000	20	Stress. Acoustic trauma	96	-88
6	F	42	5	Bilateral	Tonal	4000		Stress	32	-28
7	F	41	16	Left ear	Hissing	1000	40	Stress. Sinusitis. Eustachian tube dysfunction	70	-26
8	F	50	16	Bilateral	Tonal	7500		HL induced. Noise induced	76	-40
9	F	46	18	Left ear	Tonal	450		Noise induced. Stress	32	-16
10	F	56	456	Bilateral	Tonal	7500		HL induced	60	-26
11	F	46	28	Bilateral	Hissing	5000	15	Tympanoplasty	40	-16
12	M	53	420	Bilateral	Ringling	7000	10	Stress	54	-30
13	M	48	175	Left ear	Ringling	6300	2	Stress	34	-20
14	F	55	15	Left ear	Tonal	7000		Sudden HL	42	-10
15	M	60	5	Left ear	Hissing	6000	20	HL induced	54	-24
16	M	40	36	Right ear	Tonal	6000		Stress	46	-30
17	M	50	180	Bilateral	Tonal	10000		Noise induced. Stress	74	-30
18	M	59	36	Bilateral	Hissing	8000	12	HL induced	32	-28
19	M	41	1	Bilateral	Hissing	13500	15	Stress induced	66	-36
20	M	46	4	Left ear	Ringling	3500	2	Eustachian tube dysfunction	58	-48
21	M	59	24	Right ear	Hissing	6000	20	HL induced	78	-18
22	F	43	1	Bilateral	Tonal	4000		Eustachian tube dysfunction	32	-28
23	M	44	32	Bilateral	Ringling	4500	1	HL induced	74	+6
24	M	63	6	Bilateral	Hissing	7000	15	Stress. Acoustic trauma	68	+12
25	M	64	84	Bilateral	Hissing	7000	15	HL induced. Stress	32	+2

THI: Tinnitus Handicap Inventory; HL: hearing loss

nitus bilaterally or centrally, 8/25 (32%) on the left ear, and 3/25 (12%) on the right ear. Regarding the tinnitus sound, 11/25 (44%) patients referred to a hiss, 8/25 (32%) to a pure tone, and 6/25 (24%) to a ringing sound. The average tinnitus pitch of the 25 patients was 5790 ± 2838 Hz.

Counseling

Most participants enrolled in this study after a tortuous itinerary, including unsuccessful visits to primary care doctors, physiotherapists, homeopaths, acupuncturists, and internet searches, which intensified their distrust in tinnitus therapies. The main goal of our counseling session was to undo the negative perceptions of tinnitus mechanisms and to highlight the real expectations from tinnitus therapies. Therefore, the participants took part in a unique counseling session of approximately one hour on the elucidation of tinnitus mechanisms and how to manage it. First, an explanation of the whole auditory system, with special emphasis on the neural part, was provided. The main mechanisms of neural coding of frequency (tonotopy) and in-

tensity (firing rate) of sound were clarified. This allowed introducing tinnitus mechanisms as plastic compensation reactions to peripheral deprivation of the auditory system. Neural connections between the auditory and the limbic and autonomic nervous systems were also explained in this context, clarifying the basis for the strong emotional reactions to tinnitus, namely, annoyance, irritability, stress, anxiety, panic, and depression. Most participants acknowledged this explanation, being able to clearly identify their own emotional symptoms.

After the tinnitus subjects were instructed on the functioning of the whole auditory system, the basic principles of Jastreboff's neurophysiological model could be easily introduced^[7,8]. The tinnitus subjects were taught that the strong emotional reactions of tinnitus could be greatly decreased by blocking the connections between the auditory and the limbic and autonomic nervous systems by taking advantage of brain plasticity. Since this is a slow process, tinnitus patients should not expect a rapid effect from the treatment and should follow the treatment for

several months. Finally, once the participants promised their adherence to this slow treatment, they were enrolled for a 4-month sound therapy.

Sound Therapy

The main goal of sound therapy is to decrease the strength of tinnitus-related neuronal activity^[9]. Customized broadband sound

stimuli, consisting of random noise filtered by the HL curves of each patient ear, were generated by using a custom-designed GUI. As the HL curves of both ears are used for the calculations, these stimuli are always stereo, regardless of the ear location of the tinnitus. Schaette and Kempter,^[17] have demonstrated that this filtered noise (broadband noise with the same spectrum as the HL curves) reverses the increase of firing rate and gain induced by tinnitus

These customized broadband stimuli were given to the participants in mp3 format with the recommendation that they listen to them using a smartphone with good quality headphones for one hour per day for 4 months. Furthermore, they were trained in the correct adjustment of stimuli volume to a level just below the level of tinnitus (the mixing point)^[7].

Outcome Measure

A self-report outcome, a validated Spanish version of the THI, was used to assess the severity of tinnitus.^[19] Participants were instructed on the filling of this questionnaire during their first visit to our laboratory. Initial THI values are summarized in the last-but-one column of Table 1. According to the Spanish grading of tinnitus severity,^[19] 8/25 (32%) participants had a mild handicap ($18 \leq \text{THI} \leq 36$), 7/25 (28%) suffered from moderate handicap ($38 \leq \text{THI} \leq 56$), and 10/25 (40%) had a severe handicap ($58 \leq \text{THI} \leq 100$). After an assessment of the initial values of THI, the participants were requested by email to fill in a new THI value each month until the end of treatment. A decrease of 20 points in the THI score is usually considered to be clinically significant^[8].

Statistical Analysis

All data were analyzed using Matlab (The Mathworks Inc, Natick, MA, USA). *t* test analysis was applied to evaluate whether the mean THI outcomes before and after the treatment were significantly different. Statistical significance was set at 0.05.

RESULTS

Of the 25 participants completing the study, 22 benefited from the treatment, while 3 failed to get any relief. The THI reduction—(29

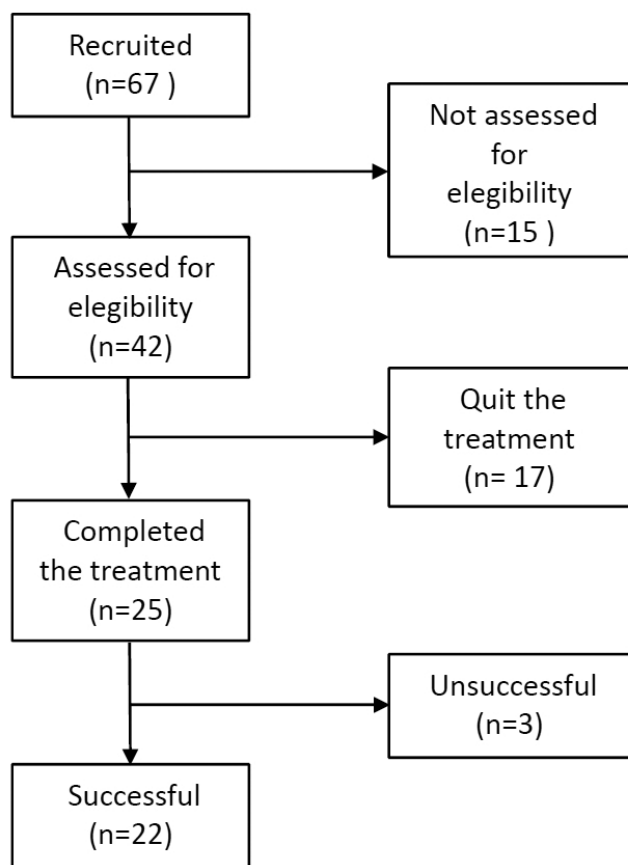


Figure 1. Flow diagram of participants.

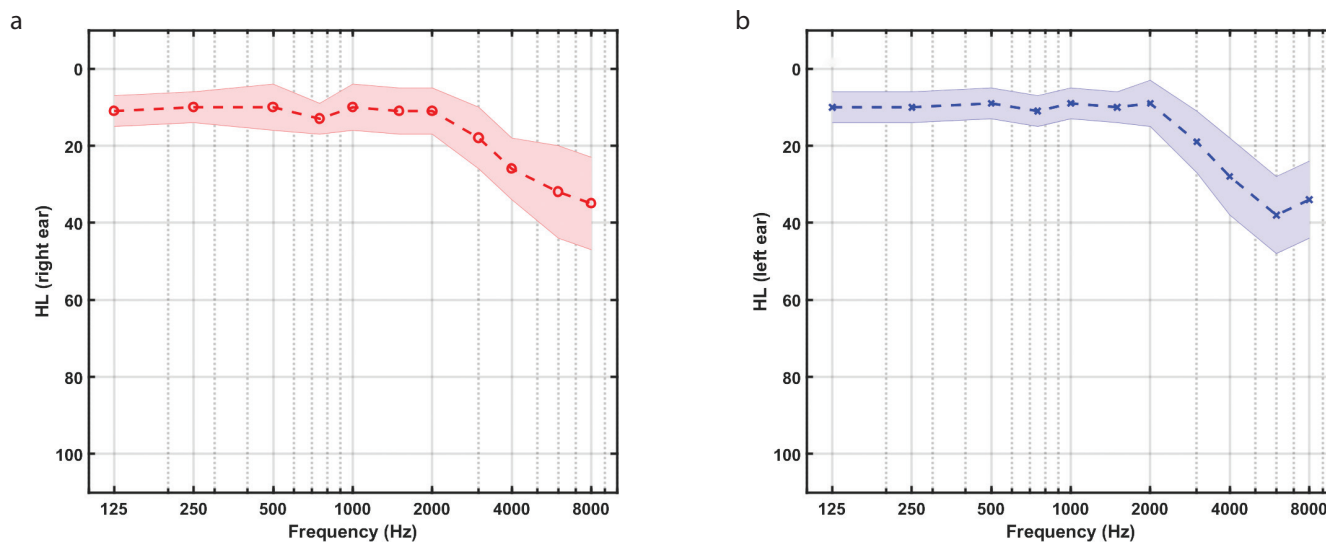


Figure 2. a, b. Mean HL for (a) right ear and (b) left ear. Shaded areas around the HL curves display the 95% confidence intervals. HL: hearing loss.

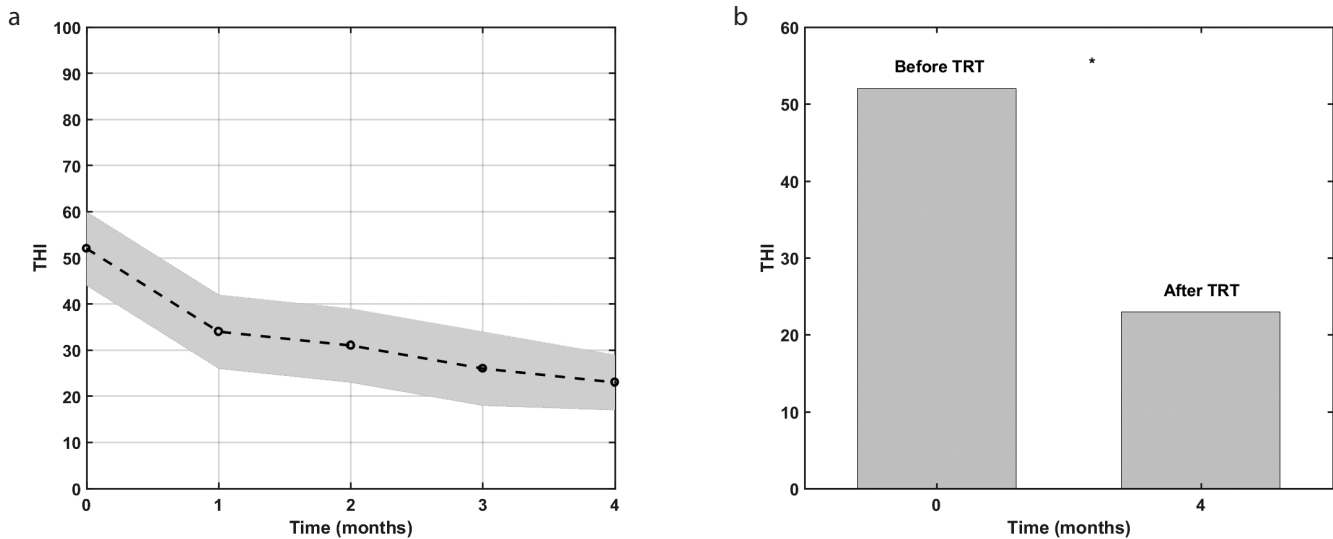


Figure 3. a, b. (a) THI score change over time for the described treatment. Shaded areas around the mean THI display the 95% confidence intervals. (b) Average THI scores before and after TRT treatment for the 22 successful patients. THI: Tinnitus Handicap Inventory; TRT: tinnitus retraining therapy.

points on average) for these participants is shown in the last column of Table 1. The THI change over the 4 months of the therapy for the 22 successful participants is presented in Figure 3a. The bar diagram of the mean THI scores before and after TRT treatment is shown in Figure 3b. Both means are significantly different at $p < 0.05$.

DISCUSSION

This is a non-randomized, uncontrolled, small-size observational study. The efficacy of TRT has been already demonstrated by randomized clinical trials^[8]. This study was designed for studying the added value of filtering the broadband noise, normally used in sound therapy, using the HL curves of patient. The small sample size, although appropriate for this kind of observational pilot study, has the limitation of weak statistical strength. Therefore, these results should be further confirmed by a larger-sized study.

Sixty-one percent (25 of 42) of the participants enrolled in this study completed the treatment, while 39% (17 of 42) quit before completion. A possible explanation for his high withdrawal ratio, in spite of the short duration of the treatment, is the strong wariness of the participants due to their negative experience with previous tinnitus treatments. This high withdrawal ratio is surprising as the treatment was provided free of charge^[20].

Eighty-eight percent (22 of 25) of patients completing the treatment obtained significant relief after 4 months. This success ratio is higher than 80% commonly mentioned for TRT treatments^[9]. The average THI score falls of 29 points after 4 months of treatment can be considered an excellent result when compared with those of other similar studies. The THI reduction with respect the initial value (DTHI) in the current study after 4 months of treatment is compared with the DTHI reported by other trials with longer durations. A 12-month TRT study by Jastreboff reported a DTHI of 23 points after the first 4 months^[8]. Henry et al.^[21] carried out a randomized clinical trial for 18 months for assessing the effectiveness of TRT as compared with masking. After the first 4 months, they accounted for a DTHI of 7 points.

Twelve percent (3 of 25) of patients worsened their THI score after completing the treatment (see Table 1). The THI score of patient 23 increased from 74 to 80 during the 4 months of the treatment. This THI score increase was attributed to the strong emotional reactions associated with his tinnitus. It is believed that the counseling session for this patient failed to change the strength of the functional connections between the auditory and emotional centers in the brain, and so the sound therapy was unsuccessful in decreasing his tinnitus distress^[7]. Patient 24, on the other hand, underwent a Magnetic Resonance Imaging (MRI) examination in the third month of treatment. Because he also suffered from hyperacusis, the high noise level inside the MRI scanner caused an anguish episode which significantly strengthened his tinnitus distress. Subject 25 experienced a THI increment of 2 points.

Finally, comparing columns 9 and 11 of Table 1, it is remarkable that tinnitus etiology is irrelevant to the success of the treatment, as already mentioned by Jastreboff^[8].

CONCLUSION

The results from this study support the use of personalized sound therapy, consisting of hearing loss-matched broadband noise, to treat heterogeneous tinnitus. The benefits of this treatment have been seen in just 4 months of the therapy. Considering the early benefits of this therapy, the easy design of the sound stimuli using a simple sound editing program, and the accessible delivery method through a smartphone connected to earphones, the treatment proposed in the present study could be a promising approach for a broader sample of tinnitus patients.

Ethics Committee Approval: This study was carried out in accordance with the ethical standards laid out in the 1964 Declaration of Helsinki, and was approved by the Institutional Ethical Committee of the CSIC.

Informed Consent: Informed consent was obtained from the patients who participated in this study.

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Conflict of Interest: The authors have no conflict of interest to declare.

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