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EVALUATION OF THE ØREBLUE® METHOD IN THE TREATMENT OF TINNITUS AND HYPERACUSIS: RESULTS OF A MONOCENTRIC OBSERVATIONAL EFFECTIVENESS STUDY IN 74 PATIENTS

Contributions:
A Study design/planning
B Data collection/entry
C Data analysis/statistics
D Data interpretation
E Preparation of manuscript
F Literature analysis/search
G Funds collection

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Abstract

Introduction: Øreblue® is a new treatment method for tinnitus and hyperacusis combining auditive rehabilitation and psychological therapy. The present monocentric observational retrospective study was to assess patient's judgements of its effectiveness.

Material and methods: From January 2011 to June 2015, 74 consecutive healthy patients (male/female, 51/23; median age, 51.5 years) with chronic tinnitus (without hyperacusis, 32) or hyperacusis (with tinnitus, 42) were treated according to priority at the Hearing Institute of Resources (La Rochelle, France). They were asked to rank their discomfort, quality of life, and sleep quality before and 1 month after treatment using 10-point scales ranging from 0 (no discomfort, poor quality of life, or poor sleep quality) to 10 (unbearable discomfort, best quality of life, or best sleep quality) and their global impression of change on a 10-point scale ranging from 0% (not improved) to 100% (fully improved). These data which were reported in patient medical files were retrospectively analysed in 2018.

Results: Discomfort, which was severe at inclusion (8.9±0.8), drastically decreased after treatment (change –8.5±1.3). Quality of life and sleep improved (from 2.2±1.4 and 2.0±1.9 to 8.3±1.4 and 4.9±2.1, respectively). 81.3% of the patients with tinnitus and 100% of patients with hyperacusis claimed to be fully improved. No adverse events were reported during the study.

Conclusions: The Øreblue® method was effective on discomfort related to tinnitus or hyperacusis; it greatly improved quality of life and sleep. Further studies, especially multicentric or randomised, possibly with imaging and long-term follow-up, should be performed to strengthen these encouraging findings.

Key words: music therapy • observational study • tinnitus • hyperacusis • Øreblue®

OCENA METODY ØREBLUE® W LECZENIU SZUMÓW USZNYCH I NADWRAŻLIWOŚCI SŁUCHOWEJ: WYNIKI JEDNOOŚRODKOWEGO BADANIA OBSERWACYJNEGO SKUTECZNOŚCI NA GRUPIE 74 PACJENTÓW

Streszczenie

Wprowadzenie: Øreblue® jest nową metodą leczenia szumów usznych i nadwrażliwości słuchowej będącą połączeniem rehabilitacji słuchowej i psychoterapii. Celem prezentowanego jednoośrodkowego retrospektywnego badania obserwacyjnego była ocena opinii pacjentów na temat skuteczności tej metody.

Materiał i metody: Od stycznia 2011 r. do czerwca 2015 r. 74 kolejnych zdrowych pacjentów (mężczyźni/kobiety, 51/23; mediana wieku, 51,5 lat) z przewlekłymi szumami usznymi (bez nadwrażliwości słuchowej, 32) lub z nadwrażliwością słuchową (i szumami usznymi, 42) było leczonych według pierwszeństwa w Hearing Institute of Resources (La Rochelle, France). Poproszono ich o dokonanie oceny swojego dyskomfortu, jakości życia i jakości snu, przed leczeniem i 1 miesiąc po leczeniu. W badaniu wykorzystano 10-stopniową skalę, w której 0 oznaczało odpowiednio: brak dyskomfortu, niską jakość życia lub niską jakość snu, a 10 – nieznośny dyskomfort, najlepszą jakość życia lub najlepszą jakość snu. Dodatkowo poproszono o zaznaczenie na 10-stopniowej skali, od 0% (brak poprawy) do 100% (pełna poprawa), swojego ogólnego odczucia zmiany. Dane zostały odnotowane w karcie medycznej pacjenta i w 2018 r. przeprowadzono ich retrospektywną analizę.

Wyniki: Dyskomfort, dotkliwy przed rozpoczęciem leczenia (8,9 ± 0,8), istotnie zmalał po leczeniu (zmiana: – 8,5 ± 1,3). Jakość życia i snu poprawiły się (odpowiednio z 2,2 ± 1,4 i 2,0 ± 1,9 do 8,3 ± 1,4 i 4,9 ± 2,1). 81,3% pacjentów z szumami usznymi i 100% pacjentów z nadwrażliwością słuchową stwierdziło, że ich stan uległ całkowitej poprawie. W trakcie leczenia nie zgłoszono żadnych zdarzeń niepożądanych.

Wnioski: Zastosowanie metody Øreblue® skutecznie zmniejsza dyskomfort związany z szumami usznymi i nadwrażliwością słuchową i znacznie poprawia jakość życia i snu. Przeprowadzenie dalszych badań, szczególnie wieloośrodkowych lub randomizowanych, ewentualnie z zastosowaniem metod obrazowania i długim okresem obserwacji, jest zalecane w celu potwierdzenia tych obiecujących ustaleń.

Słowa kluczowe: muzykoterapia • badanie obserwacyjne • szumy uszne • nadwrażliwość słuchowa • Øreblue®

Introduction

Hearing loss can be accompanied or preceded by hyperacusis and/or the phantom sensation of tinnitus [1]. In hearing loss, central auditory neurons adapt their responsiveness through homeostatic plasticity to maintain sensitivity but if this mechanism becomes dysregulated, a maladaptive over-amplification of peripheral inputs occurs that results in higher spontaneous or stimulus-evoked neural activity [1].

Tinnitus involves the perception of sounds in the ear or head without an external source. It sometimes coincides with hyperacusis, which involves increased sensitivity to certain frequencies or volume ranges of sound [2]. The perception of tinnitus or hyperacusis is variable and subjective between subjects depending on whether they feel it as a simple inconvenience or a disabling intrusion [3]. Tinnitus and hyperacusis are bothersome and can cause consequences: physical health problems, sleep difficulties, functional difficulties, concentration difficulties, related emotional complaints, negative thoughts, and/or poor mood [4]. According to the study by Aazh et al. [5], approximately one third of the patients had Hospital Anxiety and/or Depression scores indicating anxiety and depression; scores were related to tinnitus handicap, tinnitus loudness, and uncomfortable loudness levels. Tinnitus and hyperacusis also impact quality of life [4, 6]. Conversely, tinnitus and hyperacusis can be exacerbated by anxiety and stress [6].

There is no effective treatment for tinnitus and hyperacusis, the objective of the current treatments (e.g., medication, neurostimulation, cognitive behavioural therapy [BCT], tinnitus retraining therapy, sound therapy) being to reduce patient's discomfort. Finally, patients with tinnitus or hyperacusis are managed by a number of clinical specialists (e.g., general practitioners, otologists, audiologists, psychologists…) and have access to a wide range of therapeutic interventions [7-9]. For example, to address these symptoms, hearing aids plus habituation or desensitisation therapies like education, sound therapy, tinnitus retraining therapy (TRT), cognitive and behavioural therapy (CBT), and/or patient-centred counselling can help [8]. These methods enable subjects to understand and control their tinnitus to regain a certain quality of life by helping with stress management, defocusing, or even reducing symptom perception [10,11].

Øreblue® is a method built upon the principles of auditive rehabilitation and management of emotional symptoms. A mechanical device disseminating pleasant tailor-made music (i.e., classical music modified with filters adapted to the pathology- tinnitus or hyperacusis- and the pitch) is used during the sessions of functional hearing rehabilitation program. Pleasant music is used rather than broadband noise because it initiates dopamine release, which also promotes cortical plasticity [12,13]. This therapy takes advantage of attention and pleasure mechanisms that encourage neuronal plasticity to reverse the maladaptive over-amplification behind tinnitus [12].

The present study was conducted on data collected from a consecutive series of patients to evaluate the effectiveness of the novel Øreblue® method in patients with tinnitus and/or hyperacusis [2]. The secondary objectives were to assess the effect of this new method on other parameters such as the quality of life and sleep [2].

Material and methods

Study design

This observational retrospective study was conducted on data collected from a consecutive series of patients treated at one centre (Hearing Institute of Resources, 18 quai de Sénac de Meilhan, 17000 La Rochelle, France) from January 2011 to June 2015. Data were recorded on the patient medical files.

As this study was non-interventional and performed on previously collected data, the study protocol was not submitted to the opinion of an Institutional Review Board but declared to the CNIL (Commission Nationale de l'Informatique et des Libertés) upon consultation with the Expert Committee for the Research, Studies and Evaluations in Health (CEREES). CNIL agreement was obtained on 18 April 2018 (No.2173616v0). All patients included in the study freely provided written informed consent to participate. Computerized data were deidentified.

Included patients

To be included, patients had to be between 18 and 85 years of age, healthy (no history of disabling disease with exclusion of the tinnitus), sent to be treated between January 2011 and June 2015 to the investigational centre for a disabling, chronic (>1 year), subjective tinnitus with and without hyperacusis, resistant to usual treatments (drugs, hearing aids with or without masking, psychotherapy) for at least 6 months. Patients had to agree to work on the emotional part of their symptoms.

Pregnant or breastfeeding women, patients with anxiety disorder (claustrophobic), neurological disease (epilepsy or history of comital crises), serious psychiatric history on pharmaceutical treatment, bilateral cophosis, prescription medications that cause tinnitus, or with more than 6 months since their last tinnitus treatment were not to be included. Patients involved in malpractice litigation, or participating in another research protocol were also excluded from the study.

The Øreblue® method

This method has been developed to eliminate symptoms of tinnitus or hyperacusis. It has been built upon the principles of auditive rehabilitation (with sound therapy) and management of emotional symptoms.

Auditive rehabilitation is based on the systematisation of audio-signal processing developed by Mayfair Developments, to specifically match the patients' hearing profile and provide a progressive and personalised rehabilitation of their hearing perception. The chosen sound is based on several audiometric measures: hearing thresholds, tinnitus pitch or frequency range, tinnitus severity, and the discomfort threshold. Patients with tinnitus and hyperacusis are treated differently, and in patients with tinnitus and hyperacusis, hyperacusis is treated before tinnitus.

An experimental device connected to a headset provides personalised sound to the patient with simultaneous air (left and right ears) and bone (vibrations) conduction in order to compensate a loss of transmission and to allow alternating or concomitant actions between bone conduction and aerial conduction, participating in the functional rehabilitation of the ear.

A qualified practitioner customizes each patient's treatment. Based on the different measurements performed on the patients, he calculates and adjusts the filtering parameters (reduction and/or amplification of some frequencies) as well as the sound level to optimize the therapy efficiency. The aim of the frequency spectrum changes is to reverse the inappropriate cortical plasticity. For the tinnitus group, the sound treatment was determined according to the measurements of tinnitus (frequencies and intensities) and hearing thresholds. For hyperacusis, sound therapy was defined according to the zone of discomfort and hearing thresholds.

The protocol is designed to stimulate the brain by treating the acoustic input as actively and pleasantly as possible, reason why the use of a filtered musical song as an auditory stimulus is preferred over a broadband 'noise'. It has been proved that a pleasant music can initiate the dopamine release, which also promotes cortical plasticity. Music also has the advantage of being able to extend over the full spectra of audible frequencies.

Emotional symptoms are treated by psychological intervention. The psychological work progresses in parallel to the auditory rehabilitation to help the patient better understand the disease, and cope with disease-related emotional disorders.

Study treatment

This monocentric study involved one well-trained investigator (the corresponding author).

At the time of the treatment, the investigator determined if the Øreblue® method was required; subjects had audiometric measurements; a personalised hearing rehabilitation program was established. Patients were allocated into 2 groups depending on the presence/absence of hyperacusis at inclusion. Because hyperacusis treatment has priority over tinnitus, patients with hyperacusis were treated for hyperacusis first. For patients with hyperacusis and tinnitus, only data collected before and after hyperacusis treatment were analysed.

The therapy session consisted of 20–30 hours of rehabilitation carried out in a 2-hour listening repeated 5 times a week, every 4 to 6 weeks (rest periods). Each session therefore lasted between 6 and 9 weeks. At the end of the treatment, recommendations were given to encourage protective noise hygiene. Patients could take any other treatments for any other diseases during the whole study period.

Evaluation criteria

The main evaluation criterion was tinnitus and/or hyperacusis discomfort improvement. Tinnitus or hyperacusis were assessed by the patient before treatment (inclusion visit) and 1 month after treatment, using a 10-point numerical scale ranging from 0 (no discomfort) to 10 (unbearable discomfort) [2].

The secondary criteria were the changes in quality of life and sleep quality as perceived by the patients before and 1 month after treatment. Quality of life and sleep quality were assessed by numerical scales ranging from 0 (extremely poor quality of life or sleep quality) to 10 (best quality of life or sleep quality).

At 1-month treatment, patients were also asked to estimate by ear (if applicable) their global impression of change on a scale ranging from 0% (no improvement) to 100% (complete disappearance of tinnitus or hyperacusis). Information was collected in the medical file and de-identified before being transferred into the database at the time of the study.

In patients with hyperacusis, discomfort level (in dB) was assessed at inclusion and 1 month after treatment and then compared with the Fletcher 115 dB isosonic curve observed in normal subjects (after adjustment on Sennheiser HDA 200 transducer).

Sample size and statistical analysis

The sample size was not based on a formal statistical calculation, but instead on all the eligible subjects treated during the inclusion period within the investigator centre. The analysis population included subjects with scores for the main study criterion. Statistical analyses were done by group and all together.

Quantitative variables were described by number, mean, confidence interval (CI) 95%, standard deviation (SD), median, minimum (Min), and maximum (Max). Qualitative variables were summarised by number (*N*) and percentage (%).

The Øreblue® method was considered effective if the percentage of subjects with a 5-point improvement was of at least 75% (CI 95%).

The software used for statistical analysis was SAS® Enterprise Guide version 7.1. Data collection was done by the investigator. A data quality assurance plan was in place including anonymization, a secured database used by the investigator, and quality control.

Results

Recruitment was from January 2011 to June 2015 and the last follow-up was on April 2016. The analysis population included 74 treated patients who had completed follow-up. The patients were divided into 2 groups: Group 1, Tinnitus (32 subjects with tinnitus and without hyperacusis); Group 2, Hyperacusis (42 subjects with both tinnitus and hyperacusis).

Table 1 presents the main patient's demographic, occupational, and medical characteristics in each group. Patients, mainly male (68.9%), were between 19 and 83 years of age (median: 51.5 years). Patients were older (median age:

Table 1. Main baseline characteristics in the Tinnitus and Hyperacusis groups and overall

Characteristics			Tinnitus (N=32)	Hyperacusis (N=42)	Total (N=74)
Demographics	Age (years)	Mean (SD)	55.8 (16.5)	47.5 (13.1)	51.1 (15.1)
		Median [Min; Max]	55.5 [23; 83]	47 [19; 72]	51.5 [19; 83]
	Gender (Male)	N (%)	21 (65.6%)	30 (71.4%)	51 (68.9%)
Professional experience	Active	N (%)	15 (46.9%)	37 (88.1%)	52 (70.3%)
	Occupational noise exposure	N (%)	20 (62.5%)	13 (31.0%)	33 (44.6%)
Tinnitus	Duration (months)	Mean (SD)	67.1 (52.2)	83.6 (121.4)	76.5 (97.4)
		Median [Min; Max]	56.0 [26.0; 240.0]	48.5 [14.0; 807.0]	53.5 [14.0; 807.0]
Hyperacusis	Duration (months)	Mean (SD)	-	50.9 (83.7)	-
		Median [Min; Max]	-	36.0 [9.0; 567.0]	-
Hearing loss	(dB)	Mean (SD)	16.6 (21.2)	13.0 (21.4)	14.5 (21.2)
ENT medical history upon inclusion	Tinnitus	N (%)	32 (100%)	42 (100%)	74 (100%)
	Hearing aid	N (%)	10 (31.3%)	3 (7.1%)	13 (17.6%)
	Hyperacusis	N (%)	-	42 (100%)	-
	Hereditary	N (%)	11 (34.4%)	5 (11.9%)	16 (21.6%)
	ENT Intervention	N (%)	4 (12.5%)	2 (4.8%)	6 (8.1%)
	Otitis	N (%)	11 (34.4%)	6 (14.3%)	17 (23.0%)
	Blocked ear sensation	N (%)	1 (3.1%)	36 (85.7%)	37 (50.0%)
	Both ears	N (%)	1 (3.1%)	34 (81.0%)	35 (47.3%)
	Right ear	N (%)	1 (3.1%)	34 (81.0%)	35 (47.3%)
	Left ear	N (%)	1 (3.1%)	36 (85.7%)	37 (50.0%)
	Deafness	N (%)	22 (68.8%)	23 (54.8%)	45 (60.8%)
	Vertigo	N (%)	3 (9.4%)	3 (7.1%)	6 (8.1%)
Concomitant treatments taken by 10% of patients or more	1 = Hypertension	N (%)	10 (31.3%)	10 (23.8%)	20 (27.0%)
	2 = Cholesterol	N (%)	9 (28.1%)	8 (19.0%)	17 (23.0%)
	3 = Cardiology	N (%)	4 (12.5%)	7 (16.7%)	11 (14.9%)
	4 = Antidepressant	N (%)	6 (18.8%)	4 (9.5%)	10 (13.5%)
	5 = Stomach	N (%)	6 (18.8%)	3 (7.1%)	9 (12.2%)
	6 = Anxiolytic	N (%)	3 (9.4%)	5 (11.9%)	8 (10.8%)
	Combinations of interest				
	1 + 3	N (%)	4 (12.5%)	6 (14.3%)	10 (13.5%)
	1 + 2	N (%)	5 (15.6%)	6 (14.3%)	11 (14.9%)

dB: decibel; ENT: ear, nose, throat; Max: maximum; Min: minimum; N: number of subjects; SD: standard deviation; -: not applicable

55.5 versus 47 years) and less frequently active (46.9% versus 88.1%) in the Tinnitus than in the Hyperacusis group. Occupational noise exposure was more frequent in the Tinnitus than in the Hyperacusis group (62.5% versus 31.0%). More than one quarter of subjects (27.0%) were treated for hypertension, slightly more in the Tinnitus than in the Hyperacusis group (31.3% versus 23.8%). Similarities in concomitant treatments in patients from the Tinnitus and Hyperacusis groups indicated that patients had similar health profiles, although treatments were usually more frequently prescribed in the Tinnitus group.

At inclusion, tinnitus and hyperacusis were present for 14 to 807 months (median around 4 years in both groups). Hyperacusis (median duration: 36.0 months) tended to follow tinnitus (median duration: 48.5 months) in the Hyperacusis group. There was a drastically lower proportion of uni- or bilateral blocked ear sensation in the Tinnitus than in the Hyperacusis group (3.1% versus 85.7%). In comparison, mean hearing loss in the Tinnitus group was higher than in the Hyperacusis group (16.6±21.2 versus 13.0±21.4); this was consistent with the higher frequency of patients using hearing aid (31.3% versus 7.1%). In total, 5 subjects (6.8%) had severe disability, 2 (6.3%) in the Tinnitus group and 3 (7.1%) in the Hyperacusis group. Almost 70% of subjects in the Tinnitus group had high frequency tinnitus (more than 3000 Hz) with a very variable auditive intensity (2 to 26 dB).

Table 2. Pre- and post-treatment evaluation of tinnitus and hyperacusis discomfort by the patients per group and overall

Discomfort		Tinnitus (N=32)	Hyperacusis (N=42)	Total (N=74)
At inclusion	Mean (SD) [CI 95%]	8.9 (0.8) [8.6; 9.2]	9.0 (0.8) [8.7; 9.2]	8.9 (0.8) [8.8; 9.1]
	Median [Min; Max]	9.0 [7; 10]	9.0 [8; 10]	9.0 [7; 10]
At final evaluation	Mean (SD)	1.0 (1.5) [0.4; 1.5]	0.0 (0.0) [0.0; 0.0]	0.4 (1.1) [0.2; 0.7]
	Median [Min; Max]	0 [0; 5]	0 [0; 0]	0 [0; 5]
Change from inclusion	Mean (SD)	–7.9 (1.6) [–8.5; –7.3]	–9.0 (0.8) [–9.2; –8.7]	–8.5 (1.3) [–8.8; –8.2]
	Median [Min; Max]	–8.0 [–10; –4]	–9.0 [–10; -8]	–9.0 [-10; –4]
Variation from inclusion	N	32	42	74
Improvement of less than 5 points or stabilization or degradation	N % [CI 95%]	1 3.1% [0.1; 16.2%]	0 0.0% [0; 8.4%]	1 1.4% [0.0;7.3%]
Improvement of at least 5 points from inclusion	N	31	42	73
	% [CI 95%]	96.9% [83.8; 99.9%]	100.0% [91.6; 100.0%]	98.6% [92.7;100.0%]

CI: confidence interval; Max: maximum; Min: minimum; N: number of subjects; SD: standard deviation

Table 3. Pre- and post-treatment evaluations of quality of life and sleep quality by the patients per group and overall

			Tinnitus (N=32)	Hyperacusis (N=42)	Total (N=74)
Quality of life	At inclusion	Mean (SD) [95% CI]	2.9 (1.4) [2.4; 3.4]	1.6 (1.1) [1.3; 2.0]	2.2 (1.4) [1.9; 2.5]
		Median [Min; Max]	3 [1; 7]	2 [0; 3]	2 [0; 7]
	At final evaluation	Mean (SD) [95% CI]	7.9 (1.7) [7.3; 8.5]	8.6 (1.1) [8.3; 9.0]	8.3 (1.4) [8.0; 8.7]
		Median [Min; Max]	8 [3; 10]	9 [4; 10]	9 [3; 10]
	Change from inclusion	Mean (SD) [95% CI]	5.0 (1.6) [4.4; 5.6]	7.0 (1.5) [6.5; 7.5]	6.1 (1.8) [5.7; 6.6]
		Median [Min; Max]	5 [1; 8]	7 [2; 10]	6 [1; 10]
Sleep quality	At inclusion	Mean (SD) [95% CI]	1.4 (1.7) [0.8; 2.0]	2.5 (1.9) [1.9; 3.1]	2.0 (1.9) [1.6; 2.5]
		Median [Min; Max]	1 [0; 6]	2 [1; 7]	1.5 [0; 7]
	At final evaluation	Mean (SD) [95% CI]	5.6 (1.7) [5.0; 6.2]	4.4 (2.3) [3.7; 5.1]	4.9 (2.1) [4.4; 5.4]
		Median [Min; Max]	6 [1; 8]	4 [1; 9]	5 [1; 9]
	Change from inclusion	Mean (SD) [95% CI]	4.3 (1.5) [3.7; 4.8]	1.9 (1.8) [1.3; 2.4]	2.9 (2.0) [2.4; 3.4]
		Median [Min; Max]	4 [1; 7]	2 [–1; 7]	3 [–1; 7]

CI: confidence interval; Max: maximum; Min: minimum; N: number of subjects; SD: standard deviation

Patients from the Tinnitus group have had at least 3 sessions (Min–Max: 3–4) and patients from the Hyperacusis group at least 4 sessions (Min–Max: 4–5). The median number of sessions needed was 4 in both groups.

According to numerical scores, discomfort upon inclusion was severe and similar in both groups (median: 9.0; scores ranging from 7 to 10). At the final evaluation (1 month after the last session), most subjects in both groups reported little discomfort: median scores were 0.0 for both groups. In addition, most subjects in both groups had discomfort improvement of at least 5 points. Finally, more than 75% of subjects in each group had an improvement in their discomfort of at least 5 points. Therefore, according to the predefined success criteria, the Øreblue® method was considered effective for both groups. Refer to Table 2 for more details.

The quality of life was very poor at inclusion: the median score was 3 for the Tinnitus group and 2 for the Hyperacusis group. At the final assessment (1 month after treatment), median score was 8 for the Tinnitus group and 9 for the Hyperacusis group, indicating a major improvement for both groups (Table 3). The quality of sleep was very poor upon inclusion with a median score of 1 for the Tinnitus

Table 4. Decrease in post-treatment tinnitus or hyperacusis symptoms

Decrease in post-treatment		N (%) [95% CI]
Tinnitus (N=32)		
Per category	0%–50%	0 (0.0%) [0.0%; 10.9%]
	50%–80%	6 (18.8%) [7.2; 36.4%]
	80%–100%	26 (81.3%) [63.6; 92.8%]
Hyperacusis (N=42)		
Right ear	100%	42 (100.0%) [91.6; 100.0%]
Left ear	100%	42 (100.0%) [91.6; 100.0%]

CI: confidence interval; N: number of subjects

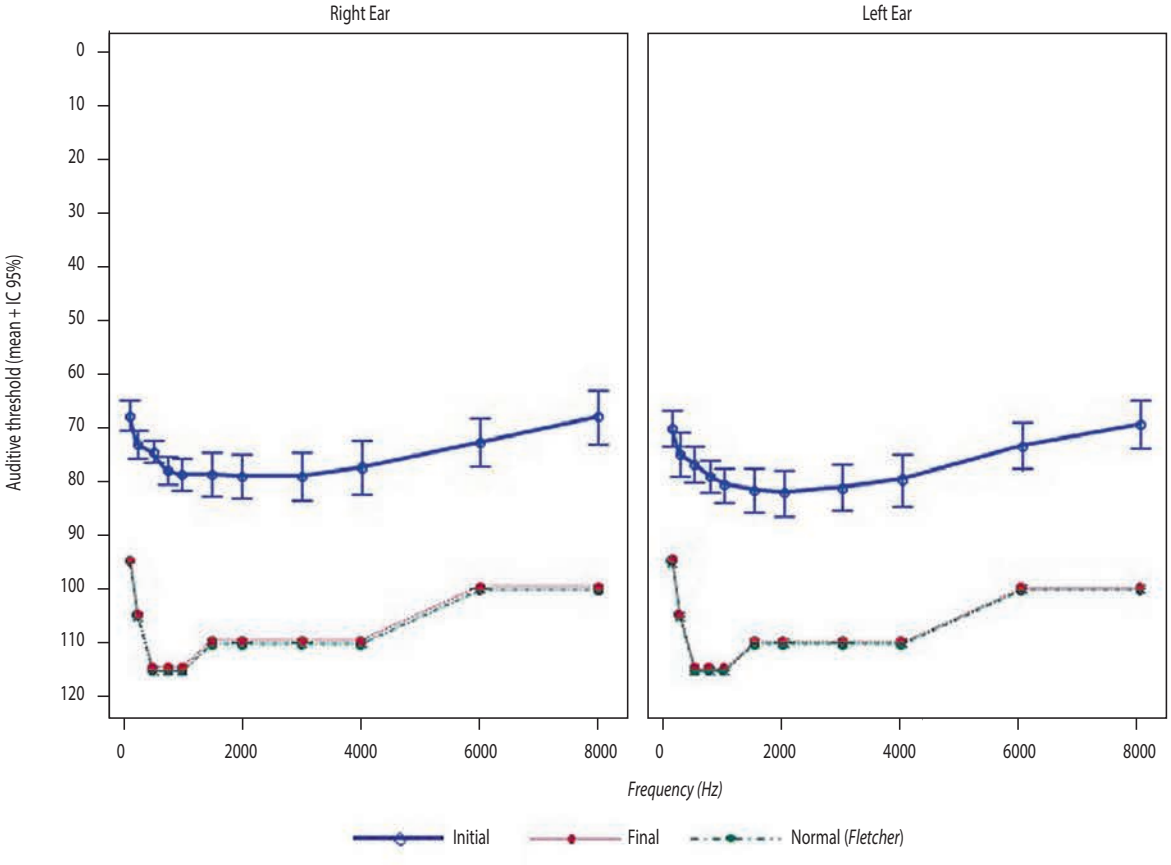

Figure 1. Discomfort level (dB) before and after hyperacusis treatment with 115 dB Fletcher's isosonic curve of a basic subject from the Hyperacusis group

group and 2 for the Hyperacusis group. One month after treatment, these scores reached 6 for the Tinnitus group and 4 for the Hyperacusis group (Table 3). This improvement (+4 and +2 points respectively) was lower than for quality of life (+5 and +7 points).

At the final evaluation, 26 subjects in the Tinnitus group reported a decrease in their symptom of at least 80% and among them, 20 reported a 100% decrease. In the Hyperacusis group, all subjects reported disappearance of their symptom for both ears (Table 4). Moreover, for each ear, the Fletcher 115 dB isosonic curve in hyperacusis patients was similar to the curve of normal subjects and differed from that before treatment (Figure 1).

No adverse events were reported during the study.

No defects in the NB#001 device were observed during the study.

Discussion

This monocentre investigator observational study demonstrates the effectiveness of the Øreblue® method in healthy patients with disabling hyperacusis or chronic, subjective tinnitus resistant for at least 6 months to usual treatments (drugs, hearing aids with or without masking, psychotherapy). The Øreblue® method drastically reduces discomfort related to tinnitus and/or hyperacusis and improves quality of life and sleep quality.

Although few epidemiological data are available in the literature, the age of included patients were consistent with those of patients with tinnitus [14,15]. According to the study by Anari et al. [16], 86% of patients attending tinnitus clinics with a primary complaint of hyperacusis also had tinnitus. In the present study, as patients were to have tinnitus to be included, 100% of the patients with hyperacusis had tinnitus. The proportion of professionally active patients was higher in Hyperacusis group as compared to the Tinnitus group, which coincides with the fact that they were on average 8 years younger. A similar age difference was also pointed out by some authors [16]. In addition, blocked ear sensation was more frequent in hyperacusis patients (>80%). Conversely, occupational noise exposure was much more frequent in tinnitus patients (>60%).

The data collected were also consistent with the literature showing before treatment a major impact on patient-reported quality of life [3,10]. Sleep was also very disturbed in both groups before treatment. This is common because subjects with tinnitus (all the subjects in this study) can hear it during the night. Improvement in sleep quality was high following treatment although minor than for quality of life. This was not surprising since this criterion is linked to multiple other factors.

The number of sessions required usually ranged between 3 and 4 for tinnitus and was 4 for hyperacusis. Usually, about 30 weeks are thus required to eliminate tinnitus and/or hyperacusis discomfort. Given that tinnitus lasted >4.5 years for 50% of the patients, 30 weeks are acceptable.

To the best of our knowledge, no study used a similar method (and tool). However, it can be hypothesized that the customized music stimulation is the closest method. According to the review by Cima et al. [9], only one randomized controlled trial has showed the benefit of customized music stimulation. However, this study which involved 34 patients showed that the personalized music therapy based on tinnitus characteristics significantly decreased the levels of tinnitus than non-customized classical music.

The present study has some limitations. Firstly, the present study was not controlled as data were collected from only one centre where all eligible patients received the same treatment. Therefore, a placebo effect could not be ruled out. However, it seems difficult to hypothesize that the results reported during this study only represented a placebo effect. Secondly, patients were followed-up for 1 month after the end of the treatment. Long-term results would be useful to confirm patient improvement over time. Thirdly, since subjects were recruited in a consecutive case series there was no sample size calculation. Fourthly, the study sample was not balanced, with a third of patients being men, whereas according to a recent epidemiology study performed in the United Kingdom [17], the incidence rates for tinnitus were similar for men and women. In addition, the measurement criteria were largely subjective, although this is logical due to the nature and specificity of the symptoms. Only numerical scales were used instead of more thorough questionnaires, especially for quality of life measures. There are several instruments in use for assessing the level of severity of tinnitus complaints, and in particular the Tinnitus Handicap Inventory (THI), which was developed to measure the impact of tinnitus on daily life [9]. However, when data collection started (January 2011), the French version of the THI (fTHI) was just validated and not commonly used in clinical practice [18]. Finally, the performance of the mechanical and psychological parts of the method were not evaluated separately. However, to the best of our knowledge at the time of the study, there was no common standard for assessing tinnitus specific complaints [4]. In addition, the present study was monocentric and involved one well-trained investigator (the corresponding author) both of which guaranteeing the optimization of the results. It can thus be hypothesised that the benefit of the treatment would probably be lower if the study would have been multicentric or would have involved different investigators. Multicentric and/or randomised studies are now required to provide a better estimate of the efficacy of the Øreblue® method taking into account the variability related to the different multidisciplinary teams who will use it to treat patients. In addition, studies with imaging could be helpful to try to understand the underlying factors for improvement. Finally, there is no data in the study that question the safety of the method nor of its device although this was not one of the objectives of the study. Despite its limitations, this study shows that the Øreblue® method was effective on discomfort related to tinnitus and hyperacusis and greatly improved quality of life and with a lesser extent quality of sleep.

In the context of P4 medicine (predictive, preventive, personalised, and participatory) [19,20], Øreblue®, which is a tailor-made method to treat tinnitus and/or hyperacusis, 2 symptoms that can only be quantified and described by patients, demonstrates the interest of combining individualised technical (acoustic rehabilitation) and human (psychological therapy) methods for the benefit of the patient.

Conclusions

The clear improvement in patients with tinnitus and/or hyperacusis observed one month after treatment with the novel Øreblue® method suggests the effectiveness of the method to relieve tinnitus and/or hyperacusis and to improve its consequences, impaired quality of life and sleep quality. Further studies, especially multicentric studies and/or randomised studies, possibly using imaging and long-term follow-up, should be performed to strengthen these encouraging findings.

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Conflict of Interest

The first author has patents relevant to the work. No conflict of interest in relation with the present article for the second author. Within the past 36 months, the second author has received fees from Arkopharma (advisory board) and from Matimo (article publication).

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