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Unexpected possibility to treat tinnitus as an inflammation process: a case-report

The prevalence of tinnitus in general population is quite common among adults. Generally, the recommendations on its treatment are scanty, there is not any medication which proved its effectiveness in resolving tinnitus at the moment. One of the reasons for such treatment problem is variety of potential causes of tinnitus which can be unrecognized.

We presented the case of a 41-year-old female with severe left-sided tinnitus, which made it difficult to sleep and limited her ability to work. The patient had several potential causes of the development of tinnitus, mainly of an inflammatory nature, but the standard anti-inflammatory treatment was not effective, therefore an attempt was made to manage the patient with the bioregulatory agent Traumeel S. The treatment turned out to be extremely effective already on the first day of the drug use and later made it possible to resolve the symptoms of tinnitus completely. Moreover, laboratory indicators of systemic inflammatory response improved, and the positive trend of these changes persisted for 5 months after the end of treatment with Traumeel S.

Described clinical case addresses an important problem of clinical practice of a family physician, – therapy of tinnitus associated with chronic inflammatory process including nonconventional approaches of the systemic inflammation control.

Key words: *tinnitus, treatment, inflammation, bioregulatory agents.*

The prevalence of tinnitus in general population is 10% among adults, with approximately half of those characterising buzzing in ears as moderately annoying, very annoying or having significant influence on their usual ways of living [3]. Tinnitus seems to be a condition that does not have considerable significance for the prognosis of a patient, but it impairs quality of life. The causes of tinnitus development are diverse (table 1).

Recently, the first guidelines on management of tinnitus were generated by American Academy of Otolaryngology – Head and Neck Surgery Foundation [14]. In May 2017, British Tinnitus Association presented the recommendations concerning this problem to general practitioners on the website www.tinnitus.org.uk [2]. At the same time, both documents state that the options to cure tinnitus, including the use of medicines, are more than scanty.

Generally, the recommendations come down to consulting due to the mental status of a patient, who constantly suffers buzzing in ears that annoys and disturbs their daily living, with the aim to correct the anxiety and depression, whose development is possible in this clinical setting, and to delivering sound therapy [2, 14]. It is noted that usually tinnitus stays with a patient forever, if the cause cannot be found and/or fully eliminated.

Table 1

Potential causes of tinnitus (modified from [3])

Group of causes	Cause
Related to ear pathology	
Most frequent	Hearing loss (including presbycusis), cerumen impaction, noise exposure
Infections	Otitis media, labyrinthitis, mastoiditis
Tumors	Schwannoma
Ototoxic drugs	Immunosuppressive, non-steroidal anti-inflammatory drugs, analgesics, antimicrobials, antineoplastic products, glucocorticoids, diuretics
Other	Meniere's disease, vertigo, otosclerosis, Eustachian tube dysfunction, hyperacusia
Neurological and psychological	
Psychological	Anxiety, depression, emotional trauma
Infections	Meningitis
Tumors	Meningioma
Other	Migraine, disseminated sclerosis, epilepsy, loss of consciousness
Traumatic and orofacial	
Orofacial	Temporomandibular joint damage
Traumatic	Traumas of head and neck
Cardiovascular, endocrine, and metabolic	
Cardiovascular	Hypertension
Endocrine and metabolic	Diabetes mellitus, hyperinsulinemia, hypothyroidism, hormonal modifications of pregnancy
Rheumatologic and immune-mediated	
	Rheumatoid arthritis, systemic lupus erythematosus etc.
Other	
	Genetic disposition
	Obesity
	Smoking and alcohol abuse

Described clinical case addresses an important problem of clinical practice of a family physician, – therapy of tinnitus associated with chronic inflam-

matory process including nonconventional approaches of the systemic inflammation control.

Materials and methods

A patient, aged 41, female, Caucasian, sought medical help from a family physician at the outpatient clinic, complaining of apparent buzzing in the left ear, which disturbed sleep and discharge of duties. Tinnitus developed one week prior to the visit for no apparent cause, and its intensity tended to increase over time. The character of the buzzing was neither monotonous nor pulsating. The body temperature did not raise, no other symptoms occurred. For the last 2 years, the patient has had two similar episodes that lasted up to 7–10 days and disappeared without treatment.

The patient considered tinnitus to be associated with chronic indolent sinusitis (occasionally nasal discharge with purulent constituent, sense of discomfort in the projection zone of frontal sinuses) and took the naturopathic drug (Sinupret® Extract, Bionorica SE, Germany) for several days with no effect. Previously, patient took this drug during exacerbation of sinusitis. Before the visit to the family physician, the buzzing in the ear became significant, it led to sleep disturbance and failure to discharge employment duties. The clinical picture added with painful chewing on the left side in the area of temporomandibular joint. The patient associated this with the episodes of third molar eruption and the existing dental problem in the area of devitalized upper left premolar and molar teeth, sometimes complicated with gingivitis, and took modified release diclofenac (25 mg rapid release and 50 mg sustained release) one time with no effect as well, since tinnitus persisted with the tendency of greater symptom intensity.

Life history: in the last 2 years, the patient has been undergoing careful examination due to the setting of increase of blood pressure (140–160/80–100 mm Hg). She has alimentary obesity, insulin resistance and hyperinsulinemia, though without diabetes mellitus, hypertension without left ventricular hypertrophy/systolic dysfunction or other target organs damage. She constantly receives antihypertensive drug moxonidine 0.4 mg once daily. Patient also has a history of dyslipidemia – secondary mild hypertriglyceridemia (triglyceride level of 2.17 mmol/L). A year ago, the patient was diagnosed with non-alcoholic fatty liver disease with minimal activity (alanine aminotransferase 74.8 U/L, aspartate aminotransferase 34.9 U/L). For the last two years, few blood analyses have discovered increased inflammatory markers (table 2).

At the moment of examination (27.04.2017), patient complained of buzzing in the left ear only with no pain in the area of the left temporomandibular joint.

Physical examination findings (27.04.2017): satisfactory condition, body temperature 36.4 °C, height 172 cm, body weight 133 kg, body-weight index

Table 2

Dynamics of laboratory inflammatory markers (anamnestic data)

Laboratory parameter	12.03.2015	31.05.2016	1.07.2016	15.08.2016	08.11.2016
Fasting glucose, mmol/L	5.43	5.02	–	–	5.59
Glycated hemoglobin, %	–	–	–	–	5.83
Insulin, $\mu\text{U/mL}$	–	–	–	–	46.6
HOMA index	–	–	–	–	11.58
Leucocytes, $\cdot 10^9/\text{L}$	11.5	11.8	12.34	12.28	11.57
Neutrophils, $\cdot 10^9/\text{L}$	7.3	–	7.9	7.19	7.26
Erythrocyte sedimentation rate, mm/h	36	28	35	13	49
C-reactive protein, mg/L	–	–	–	18.89	–

44.96 kg/m² (obesity of 3rd degree). Skin integument and visible mucous membranes showed no abnormalities. Palpable lymph nodes were not swollen. Blood pressure 143/78 mm Hg, heart rate 85 bpm, regular. During auscultation of the heart and lungs abnormalities were not found. Abdomen was enlarged in size due to subcutaneous fat, superficial and profound palpation didn't discover any abnormality. We also found enlarged liver, +4 cm, sharp border, elastic when palpated. Peripheral edema was absent. Examination of acoustical duct on both sides revealed no abnormalities.

The patient had examination by ENT-specialist (ear, nose and throat specialist); CT imaging of upper/lower jaw and paranasal sinuses was performed, as well as audiogram. No signs of the pathology obviously responsible for the development of tinnitus were revealed.

Results

The patient had a pattern of potential causes of development of the buzzing in ears including noise exposure, symptoms on the side of temporomandibular joint, hypertension, hyperinsulinemia, and obesity. Apart from that, the factors were pointed out whose connection with the development of buzzing in ears is less established and nevertheless, is possible; these include clinical signs of sinusitis with no apparent structural changes in CT image and the dental problem. An additional factor is the patient's anxiety. None of these factors can be directly associated with the development of tinnitus; most probably, their effects are combined in this clinical case. In fact, almost all the mentioned constituents of the pattern of tinnitus causes in this case have one pathogenesis component, i. e. systemic or local inflammation (table 3).

The patient also informed about pro-inflammatory state – in the series of laboratory analyses she was diagnosed with persistent leukocytosis 9–

$12 \times 10^3/\text{L}$, increased index of erythrocyte sedimentation rate (up to 49 mm/h), as well as increased level of C-reactive protein, whilst diseases of connective tissue or other causes of systemic inflammation, except for the ones enumerated, had been excluded.

Table 3

Pattern of patient's tinnitus causes

Systemic inflammation	Local inflammation
Hypertension	Symptoms (pain at chewing) in the area of left temporomandibular joint
Obesity	Clinical signs of sinusitis
Hyperinsulinemia and insulin resistance	Dental pathology
Dyslipidemia*	
Cause not associated with inflammation	
Noise exposure	Anxiety

*Is not a cause of tinnitus, however, influences systemic inflammatory reactions and function of endothelium.

Thus, it appeared interesting to influence inflammation as a basis of the majority of potential tinnitus causes in the patient. Diclofenac which had been taken by the patient in terms of self-treatment, despite of being an interesting strategy, did not produce a positive result.

We offered the patient a different approach directed at control and resolution of inflammation [13] with the use of bioregulatory therapy preparation Traumeel S (TS, Biologische Heilmittel Heel GmbH, Germany). TS is a preparation of bioregulatory therapy with number of plant and mineral ingredients which favors resolution and control of inflammation, instead of suppression thereof; it is effective both in local and systemic inflammation [10].

We suggested an initiating regimen of 1 tablet of TS sublingual every 15 minutes during 2 hours with subsequent switch to the regimen of 1 tablet 3 times a day, another visit was planned after 1 month of treatment to evaluate effectiveness of the therapy and to control the inflammatory markers.

When planning the therapy with TS, we asked the patient to characterize the intensity of the tinnitus symptom on VAS scale of 0 (no symptom) to 10 (the most intense tinnitus for the preceding days) every two hours in the waking periods of the preceding 4 days when she was administering other preparations. The patient was also suggested to keep a diary with an assessment of VAS index during the therapy with TS in the same format (assessment every two hours in the waking period) indicating the time of the drug administration in the course of few days after the start of the therapy (figure).

A. First day of TS administration with initiating stage of «6 tablets in 2 hours» (28.04.2017)*

*Red arrow marks the drug administration schedule of 1 tablet every 15 min during 2 h, blue arrows mark the administration of 1 tablet of TS.

B. Second day of therapy with TS, with morning intake skipped (29.04.2017)**

**Morning intake was accidentally skipped, there was a possibility to renew the therapy in the afternoon only. In view of a symptomatic relapse another course of initiating therapy was carried out. Red arrow marks the drug administration schedule of 1 tablet every 15 min during 2 h, blue arrow marks the administration of 1 tablet of TS.

C. Third day of therapy with TS (30.04.2017)***

***No data for the period of 7 o'clock in the morning (holiday). Arrows mark administration of the drug.

Figure. Dynamics of VAS-score of tinnitus symptom intensity in the patient

As seen in the given figure, prescription of TS in the initiating regimen (1 tablet every 15 minutes during 2 hours) led to an extremely fast and significant improvement, and as early as the first day of the therapy the patient did not at all experience buzzing in ears for few hours (figure, A), likewise the patient did not have tinnitus at night and did not experience difficulties with the sleep. The next day, the patient skipped the morning intake of the drug and was able to renew the treatment in the afternoon only. It was the day when impairment was noted and the buzzing in ears emerged at the maximal intensity of 3 grades on VAS, but it resolved on the background of another course of initiating therapy (figure, B). Further, there was observed a periodic occurrence of tinnitus with the intensity of 1 grade 6-8 hours after administration of the drug; however, after the application of TS, the buzzing in ears ceased suggesting a clear efficacy of TS in particular (figure, C).

After a significant progress was made in terms of decrease of tinnitus intensity, with account of pro-inflammatory state of blood of the patient due to metabolic disorders associated with alimentary obesity, it was decided to continue the therapy with TS for 1 month with subsequent control of inflammation markers.

Final examination and assessment of pro-inflammatory markers was planned to take place in 1 month from the beginning of the therapy with TS (on May 29, 2017). One month after the initiation of the therapy with TS, the patient noted a very weak buzzing of not more than 1 grade on VAS when waking in the morning; it resolved completely within half an hour and did not recur throughout the day. At the assessment of inflammation markers, we observed some decrease in white blood cell count and neutrophil count, C-reactive protein as well as apparent decrease in erythrocyte sedimentation rate as compared to the previous data (table 4). Although we did not expect any significant changes in these indices associated with TS monotherapy for such a short term, the results were totally promising.

Table 4

**Markers of the systemic inflammation of the patient
after 1 and 5 months of TS therapy with sublingual route
of administration as compared to the previous data**

Index	Previous result (2016)	29.05.2017	27.10.2017
White blood cells, $\cdot 10^9/L$	11.57	11.4 (↓)	11.26 (↓)
Neutrophils, $\cdot 10^9/L$	7.26	7.0 (↓)	7.13
Erythrocyte sedimentation rate, mm/h	49	18 (↓↓↓)	32
C-reactive protein, mg/L	18.89	18 (↓)	18.85

The patient was given recommendations to follow work and rest schedule, maintain recommended physical activity level, and recommendations regarding the non-drug methods for prevention of cardiovascular pathology, particularly, body weight reduction, blood lipids level control. She was recommended to visit a dentist in order to solve her dental problem, and avoid noise exposure.

Discussion

The peculiarity of this case is an apparent benefit of TS in the treatment of acute unilateral undifferentiated tinnitus which was more effective than the naturopathic line preparation for sinusitis treatment or one-time administration of biphasic release diclofenac (rapid and sustained release in one capsule). In clinical practice, a family physician sometimes does not have an opportunity to examine a patient thoroughly in order to find a cause of tinnitus. Although, even after the examination performed, the cause cannot always be determined. Today, evidence based medicine does not provide any approaches to solve this clinical problem by means of drugs [3, 14]; the preparations of conventional therapy, herbal medicinal products, and the products formulated under the principles of naturopathy are generally prescribed empirically due to the cause suggested.

In this case, we judged from a number of conditions that suggested an inflammatory nature of acute tinnitus. The conventional therapy preparation of anti-inflammatory action (diclofenac) was not effective at one-time administration of the biphasic (rapid and sustained release) form. Therefore, we considered it inappropriate to continue the therapy with the medicinal product having a significant number of side effects. It was obvious that chronic systemic and local inflammatory process which was presented in the patient, associated with metabolic disorders and proved by the dynamics of inflammatory markers (white blood cell count and neutrophil granulocytes count, erythrocyte sedimentation rate, C-reactive protein), required a systemic approach and, particularly, not suppression but resolution. In this connection, we recommended the therapy with probably the only preparation available on the pharmaceutical market which is directed precisely at control and resolution of inflammation process instead of suppression thereof [5, 6].

The fact that in the same patient different preparations were subsequently applied without crossed concurrent prescription, and clear connection between TS, improvement and significant resolution of tinnitus was discovered adds valuable information to the existing evidence base of the product which has already proved itself to be an effective therapy for inflammation of different etiology [1, 11, 15]. There are literary data on non-inferiority of TS to diclofenac in treatment of acute injuries, inflammatory processes [4, 12]. At the moment, the results of recent multicenter controlled trails are available, they

confirm the efficacy of TS in the control of inflammatory processes [7-9]. However, the available literature does not contain data on treatment of acute tinnitus in patients with pro-inflammatory state.

Another aspect which is important for confirming the efficacy of TS preparation is the fact that after the apparent improvement, the patient skipped the intake of the drug, and during next days of the therapy the symptom relapsed in about 6-8 hours after the last tablet was applied, whereas after the administration of TS the clear improvement was observed in 1–2 hours. It shouldn't be considered as a placebo-effect in this case, as before TS the patient received two other agents that, according to her, she believed were effective. Thus, it is reasonable to assume that the placebo-effect would have manifested itself much earlier, yet following the therapy with these preparations the patient noted tinnitus impairment only, while the treatment with TS was started at the peak intensity of the symptom with the patient having been stressed for a few days because of the apparent buzzing in ear which disturbed sleep and discharge of employment duties.

At assessment of this case there have been some limitations. We did not assess inflammatory markers and other laboratory tests at the first visit of the patient, but considered the previous data. This approach is consistent with the present-day guidelines on management of tinnitus, whose recommendations do not require to obligatory assess the laboratory tests. Furthermore, it is unlikely that we would have received additional information important for the choice of the way to manage the patient, as it was the long-standing history of pro-inflammatory changes in blood before patient presentation to our clinic. At the same time, we carried out a laboratory testing of inflammation markers 1 month after the therapy with TS preparation in order to determine the possible changes in the pro-inflammatory state of the patient with the aim to define the treatment policy for the future. Apart from that, audiogram and consultation by the ENT-specialist were performed according to the applicable recommendations for tinnitus management; and our approach to the patient's examination is in general typical for the current clinical practice. The second potential limitation is the slightly modified dosage schedule of TS on the second day due to the skipping of the application by the patient and the relapse of the buzzing in ears. In general, the initiating therapy done twice is not appropriate strategy; however, the instructions do not contain references prohibiting such approach. In this case, second initiating regimen allowed for the fast reestablishment of the primary effect of TS therapy, assisted the patient to calm down, and demonstrated the necessity to adhere to the therapy regimen.

In conclusion, bioregulatory preparation TS can be effective in some cases of acute tinnitus, especially if there is a pattern of potential causes of its development, associated with systemic and local inflammation. In our case, TS

proved to be more effective than diclofenac as early as on the first day of the therapy.

Scientific perspective: This clinical case addresses an important problem of clinical practice of a family physician, i.e. the therapy for forms of tinnitus associated with chronic inflammatory process. Well-designed controlled trials with an appropriate number of patients are necessary for studying the data we received.

Conflict of interests. This case got Main Hans Heinrich Reckeweg Clinical Case Award 2017 established by Biologische Heilmittel Heel GmbH, Germany.

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**Неочікувана можливість лікування тинітусу
як запального процесу: клінічний випадок**

Резюме

Поширеність тинітусу в загальній популяції серед дорослих доволі висока. Загалом, рекомендації з лікування є нечисельними, на даний час не існує медикаментозної терапії, що довела ефективність у звільненні від симптому тинітусу. Однією з причин такої проблеми є різноманіття потенційних причин розвитку тинітусу, які можуть залишатись невизначеними.

Представлений випадок: жінка, 42 років, з вираженим лівостороннім тинітусом, що ускладнював сон і обмежував працездатність. У пацієнтки відзначено відразу кілька потенційних причин розвитку тинітусу, переважно запального характеру, однак стандартне протизапальне лікування не було ефективним, у зв'язку з чим була зроблена спроба ведення пацієнтки за допомогою біорегуляційного засобу Траумель С. Лікування виявилось надзвичайно ефективним вже в першу добу застосування препарату і в подальшому дало можливість повністю позбутися тинітусу. Також дещо поліпилися лабораторні показники маркерів системної запальної відповіді, причому позитивна тенденція цих змін зберігалася 5 місяців після закінчення лікування препаратом Траумель С.

Представлений клінічний випадок присвячено важливій проблемі клінічної практики сімейного лікаря – терапії тинітусу, асоційованого з хронічним запальним процесом, включно з нетрадиційними підходами до контролю системного запалення.

Ключові слова: тинітус, лікування, запалення, біорегуляційні засоби.

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**Неожиданная возможность лечения тиннитуса как воспалительного
процесса: клинический случай**

Резюме

Распространенность тиннитуса в общей популяции среди взрослых довольно высока. В основном, рекомендации по лечению немногочисленны, в настоящее время не существует медикаментозной терапии, доказавшей свою эффективность в разрешении тиннитуса. Одной из причин такой проблемы является разнообразие потенциальных причин развития тиннитуса, которые могут оставаться нераспознанными.

Представлен случай: женщина, 41 год, с выраженным левосторонним тиннитусом, затруднявшим сон и ограничивавшим трудоспособность. У пациентки отмечено сразу несколько потенциальных причин развития тиннитуса, в основном воспалительного характера, однако стандартное противовоспалительное лечение не было эффективным, в связи с чем была предпринята попытка ведения пациентки с помощью биорегуляционного средства Траумель С. Лечение оказалось чрезвычайно эффективным уже в первые сутки применения препарата и в дальнейшем дало возможность полностью избавиться от тиннитуса. Также несколько улучшились лабораторные показатели маркеров системного воспалительного ответа, причем положительная тенденция этих изменений сохранялась 5 месяцев после окончания лечения препаратом Траумель С.

Описанный клинический случай адресован важной проблеме клинической практики семейного врача – терапии тиннитуса, ассоциированного с хроническим воспалительным процессом, включая нетрадиционные подходы контроля системного воспаления.

Ключевые слова: *тиннитус, лечение, воспаление, биорегуляционные средства.*

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