GEORGIAN MEDICAL NEWS

ISSN 1512-0112

NO 3 (336) Март 2023

ТБИЛИСИ - NEW YORK

ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

Monthly Georgia-US joint scientific journal published both in electronic and paper formats of the Agency of Medical Information of the Georgian Association of Business Press. Published since 1994. Distributed in NIS, EU and USA.

GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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Содержание:

GEORGIAN MEDICAL NEWS
No 3 (336) 2023

NEW APPROACHES TO THE EVALUATION OF HERBAL DRUG EFFICACY IN CHRONIC RHINOSINUSITIS TREATMENT SCHEME BASED ON CHANGES OF QUALITY-OF-LIFE CRITERIA

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Abstract.

Assessment of quality of life (QOL) is one of the key criteria for evaluating the effectiveness of treatment in clinical trials. It is very important to pay attention to the methods of evaluation and analysis. Health-related quality of life is very important in evaluating drug efficacy. The assessment of this indicator in clinical trials is considered as an additional indicator of drug efficacy, a new tool for choosing an effective drug for clinical practice, etc.

To assess the quality of life of patients with chronic rhinosinusitis and select an effective drug such as “Gutanos” (anti-inflammatory, antimicrobial nasal drops of plant origin), we followed the recommended steps for cultural adaptation of SNOT-22 into Armenian, creating a tool for assessing patients with clinically significant sinonasal disorders. (rhinosinusitis), as well as for scientific research (Cronbach index = 0.81), the reliability of the test-retest was determined (ICC = 0.85). We found that SNOT-22 is reliable, easy to use, and can be used to facilitate daily clinical practice to highlight the impact of chronic rhinosinusitis on patients' quality of life.

Key words. Quality of life, questionnaires SNOT-22, chronic rhinosinusitis, “Gutanos”.

Introduction.

Diseases of the upper respiratory tract, especially inflammatory diseases of the nasal cavity and paranasal sinuses, are highly common diseases evaluated in outpatient settings in recent years. Chronic rhinosinusitis (CRS) has a negative impact on the health-related quality of life (QoL) of patients and health care resources. Pathogenic microbes play an insignificant role in the etiology of CRS [2,4,6,7,8,9,10,23]. Many clinical studies have shown that changes in treatment affect the quality of life of patients [3,13,14,24,29]. Over the past decades, more research has focused on patients' QoL, and the use of QoL scores has increased [1,5,12,21,26,27].

QOL criteria have independent predictive value and can be used as an objective tool for treatment efficacy assessment [5,25].

Chronic inflammatory diseases of the paranasal sinuses, like other somatic diseases, serve as an essential background for decreasing the quality of life and formation of psychoemotional disorders (PED). It was found that in chronic sinusitis there is moderately severe anxiety and depression, as well as a decrease in the quality of life of patients [16,17,18]. Some authors point to a close relationship between chronic sinusitis and sleep disorders, which are important components of PED [19]. On the other hand, there is evidence that increased anxiety, hypochondria in premorbidity can contribute to somatization, including the formation of chronic rhinosinusitis [20]. This indicates the ambiguity of the causative factors of such comorbidity.

Adequate use of antimicrobial therapy in a chronic pathological process helps to prevent the subsequent development of moderate PED, as well as clinically pronounced depression requiring the appointment of antidepressants, which is typical for chronic forms of rhinosinusitis. There is evidence that the use of adequate antimicrobial therapy (including herbal treatment) can significantly improve the quality of life of patients with chronic rhinosinusitis, including its psychoemotional component [14,15, 21,22]. However, the topic of ENT and PED comorbidity is rarely discussed in publications. This makes it relevant to study this issue, especially in Armenia, where such studies have not been conducted.

Materials and methods.

A randomized blinded controlled trial was conducted in 900 patients with chronic rhinosinusitis (time period 2014-2022), aged 15 to 18 years who were receiving standard treatment adding “Gutanos” nasal drops (experimental group) and standard treatment only (control group). A table of random numbers was used for the distribution of study participants by the compered groups. Each of the compared groups consisted of 450 patients. Standard treatment included Klacid, Polideksa spray, Akvalor spray, Klaritin and Mig (ibuprofen).

"Gutanos" was patented as anti-inflammatory, antimicrobial nasal drops of plant origin by the pharmaceutical company "Arpimed LLC". The patent for an invention No. 2753A was issued, and it was also approved by Intellectual Property Agency of RA as an invention (application No. 20130019). It can be used for prevention and cure of upper respiratory tract diseases.

The study was conducted in accordance with the Declaration of Helsinki [28] and the ICH Guideline for Good Clinical Practice [20]. A hospitalization did not take place. In the CRS-02 study, 15 to 18 years of age with bilateral CRS without nasal polyps confirmed by endoscopy (optional computer tomography). Patients were randomized on day 1 (visit 1) and control visits were scheduled after 3 days (visit 2), 1 week (visit 3), 2 weeks (visit 4), 4 weeks (visit 5), 6 weeks (visit 6). The follow-up examination was 8 weeks after scheduled (visit 7).

At each visit, patients were evaluated by the investigator for the five symptoms of the Major Symptom Score (MSSINV). Total MSS score [11, 19] had to be 6 to 12 points and rhinorrhea and pain (facial pain or headache) had to be of at least moderate intensity.

Patients recorded symptoms in a diary at five days during the screening period. The severity of each of the five symptoms was indicated on a 4-point rating scale of increasing severity (0 = none; 1 = mild; 2 = moderate; 3 = severe).

As a treatment efficacy criterion the evaluation of differences in the disease clinical symptoms and estimation of clinically significant differences in quality-of-life outcomes have been used. The Sino-Nasal Outcome Test-22 (SNOT-22) was used to evaluate the impact of rhinosinusitis symptoms on health-related quality of life (HRQoL). Visit assessed using a 0–5-point Likert scale (0 = not present / no problem; 1 = very mild problem; 2 = mild or slight problem; 3 = moderate problem; 4 = severe problem; 5 = problem as bad as it can be).

Spielberger's State-Trait Anxiety inventory has been used for the assessment of the anxiety degree in patients. The inventory consists of 40 statements divided by 2 scales. The first one (S-Anxiety) allows to evaluate a person's state anxiety level, or anxiety about an event, whereas the second scale (T-Anxiety) - the personal anxiety. Each scale has a different rating scale. In practice, the following anxiety rating scale is applicable: 30 points or less - mild form of anxiety, 31-44 points - moderate, 45 and above - severe form of anxiety.

Statistical methods.

Data was processed into Microsoft Excel 16 statistical software. Distribution was symmetric (Kolmogorov-Smirnov test). Distribution of the study variables was calculated for two compared groups – experimental and control. For analysis of the main subjective symptoms and individual anxiety level in the compared groups (experimental and control) an independent t-test was used.

For assessment of the level of change in symptoms (in score) before and after treatment in the experimental and control groups a z test was used.

Results.

Changes in major subjective and objective symptoms in the control and experimental groups were assessed for each of the seven visits.

During the first visit of the patient after the course of therapy, the doctor assessed the symptoms of chronic rhinosinusitis on a 5-point scale (0-4, 4: the symptoms are strong, 0 is absent).

Before and after therapy, the patient was assessed for quality of life using the SNOT 22 questionnaire. The severity of chronic rhinosinusitis symptoms was assessed using a 5-point scale

Table 1. *The dynamics of the major subjective symptoms in the compared groups.*

1. Nasal congestion, points							
Groups	Visits						
	1	2st	3nd	4rd	5th	6th	7th
Control	6,8±0,3	5,2±0,2	3,2±0,2	1,8±0,2	0,8±0,1	0,7±0,1	0,7±0,1
Experimental	6,5±0,2	4,9±0,2	3,0±0,2	1,5±0,1	0,4±0,1	0,2±0,1	0,2±0,1
t, p	0.83, p>0.05	0.83 p>0.05	0.56 p>0.05	1.3 p>0.05	2.8 p<0.01	3.5 p<0.01	3.5 p<0.01
2. Nasal discharge, points							
Groups	Visits						
	0	1st	2nd	3rd	4th	6th	7th
Control	6,5±0,2	5,8±0,2	3,7±0,3	2,9±0,2	2,0±0,08	2,0±0,08	2,0±0,08
Experimental	6,7±0,2	5,5±0,2	3,0±0,3	1,8±0,1	0,8±0,07	0,6±0,07	0,6±0,07
t, p	0.7 p>0.05	1.1 p>0.05	1.6 p>0.05	4.9 p<0.01	11.3 p<0.01	13.2 p<0.01	13.2 p<0.01
Groups	3. Facial pain, points						
	0	1st	2nd	3rd	4th	6th	7th
Control	4,8±0,2	3,1±0,2	2,6±0,1	1,8±0,12	0,9±0,03	0,9±0,03	0,9±0,03
Experimental	4,8±0,3	3,2±0,2	1,9±0,1	1,3±0,11	0,2±0,02	0,2±0,02	0,2±0,02
t, p	0	0.4 p>0.05	4.9 p<0.01	3.1 p<0.01	19.4 p<0.01	19.4 p<0.01	19.4 p<0.01
Groups	4. Sense of taste, points						
	0	1st	2nd	3rd	4th	6th	7th
Control	4,8±0,3	1,8±0,3	1,5±0,2	0,7±0,13	0,4±0,05	0,4±0,05	0,4±0,05
Experimental	3,8±0,3	2,3±0,3	1,3±0,1	0,4±0,1	0,1±0,06	0,09±0,05	0,09±0,05
t, p	2.4 p<0.05	1.2 p>0.05	0.9 p>0.05	2.1 p<0.05	3.8 p<0.01	4.4 p<0.01	4.4 p<0.01
5. The dynamics of total subjective symptoms, points							
Groups	Visits						
	0	1st	2nd	3rd	4th	6th	7th
Control	8,8±0,2	6,0±0,2	3,4±0,2	2,7±0,2	0,9±0,16	0,9±0,16	0,9±0,16
Experimental	7,8±0,2	5,8±0,2	3,3±0,2	1,9±0,17	0,4±0,12	0,3±0,11	0,3±0,11
t, p	3.5 p<0.01	0.7 p>0.05	0.4 p>0.05	3.04 p<0.01	2.5 p<0.05	3.1 p<0.01	3.1 p<0.01

Table 2. *The dynamics of the main objective symptoms in the compared groups.*

1. *Nasal Mucosal Edema, points*								
Groups	Visits							
	0	1st	2nd	3rd	4th	5th	6th	7th
Control	2,8±0,01	1,9±0,07	1,5±0,08	0,6±0,08	0,4±0,06	0,4±0,06	0,4±0,06	0,4±0,06
Experimental	2,8±0,01	1,7±0,07	1,3±0,01	0,6±0,07	0,1±0,06	0,1±0,06	0,1±0,06	0,1±0,06
t, p	0 p>0.05	2.0 p<0.05	2.5 p<0.05	0 p>0.05	3.5 p<0.01	3.5 p<0.01	3.5 p<0.01	3.5 p<0.01
2. Nasal discharge, points								
Groups	Visits							
	0	1st	2nd	3rd	4th	5th	6th	7th
Control	2,58±0,09	2,2±0,08	1,9±0,09	0,9±0,08	0,3±0,08	0,3±0,08	0,3±0,08	0,3±0,08
Experimental	2,7±0,1	2,0±0,08	1,4±0,09	0,7±0,07	0,1±0,06	0,1±0,06	0,1±0,06	0,1±0,06
t, p	0.9 p>0.05	1.8 p>0.05	3.9 p<0.01	1.9 p>0.05	2.0 p<0.05	2.0 p<0.05	2.0 p<0.05	2.0 p<0.05
Groups	3. Nasal mucosa hyperemia, points							
	0	1st	2nd	3rd	4th	5th	6th	7th
Control	2,8±0,07	1,8±0,09	0,9±0,09	0,4±0,07	0,2±0,03	0,2±0,03	0,2±0,03	0,2±0,03
Experimental	2,8±0,08	1,6±0,08	0,9±0,09	0,1±0,07	0,1±0,03	0,1±0,03	0,1±0,03	0,1±0,03
t, p	0 p>0.05	1.7 p>0.05	0 p>0.05	3.0 p<0.01	2.4 p<0.05	2.4 p<0.05	2.4 p<0.05	2.4 p<0.05
3. The dynamics of total objective symptoms, points								
Group	Visits							
	0	1st	2nd	3rd	4th	5th	6th	7th
Control	7,9±0,2	6,3±0,2	4,7±0,2	2,8±0,2	1,8±0,16	1,8±0,16	1,8±0,16	1,8±0,16
Experimental	7,8±0,2	5,5±0,2	3,7±0,2	2,4±0,17	0,9±0,12	0,9±0,12	0,9±0,12	0,9±0,12
t, p	0.4 p>0.05	2.8 p<0.05	3.5 p<0.01	1.4 p>0.05	4.5 p<0.01	4.5 p<0.01	4.5 p<0.01	4.5 p<0.01

Table 3. *Frequency of the disease symptoms before and after the treatment (SNOT 22 questionnaire was filled in before and after the treatment using 5points scale).*

	Symptoms	**Experimental group**			**Control group**			**z,p**
		before	**after**	**%**	**before**	**after**	**%**	
1	Need to blow nose	4.3	3.1	72.1	4.2	4.1	97.6	11.4, p< 0.05
2	Nasal obstruction	4.2	3.1	73.8	4.1	3.8	92.7	7.8, p< 0.05
3	Frequent sneezing	4.4	2.7	61.4	4.4	3.7	84.1	7.9, p< 0.05
4	Runny nose	4.5	2.3	51.1	4.5	3.4	75.6	7.9, p< 0.05
5	Cough	4	2.2	55	4	3.3	82.5	9.3, p< 0.05
6	Post-nasal discharge	4.3	1.4	32.6	4.3	4.2	4.2	11.8, p< 0.05
7	Thick nasal discharge	4.2	1.5	35.7	4.1	4.1	4	13.0, p< 0.05
8	Ear fullness	3.2	2.2	68.8	3.5	3.4	4	27.3, p< 0.05
9	Dizziness	4	3	75	4.1	3.9	95.1	8.8, p< 0.05
10	Ear pain	3.9	2.3	59	3.8	3.2	84.2	8.7, p< 0.05
11	Facial pain/pressure	3	2.4	80	3.1	3	96.8	8.2, p< 0.05
12	Loss of smell or taste	4	2.8	70	4.1	4	97.6	12.1, p< 0.05
13	Difficulty falling asleep	3.8	2.2	57.9	3.9	3.8	97.4	16.2, p< 0.05
14	Waking up at night	3.9	2.1	53.8	4	3.9	97.5	1.1,p>0.05
15	Lack of a good night's sleep	3.7	2.2	59.5	3.8	2.8	73.7	4.6, p< 0.05
16	Waking up tired	4	3	75	4.1	4	97.6	10.4, p< 0.05
17	Fatigue	4.1	3	73.2	4	3.9	97.5	10.9, p< 0.05
18	Reduced productivity	4	3.2	80	4	3.9	97.5	8.6, p< 0.05
19	Reduced concentration	3.9	2.9	74.4	4	3.2	80	2.0, p< 0.05
20	Frustrated/restless/irritable	4	3.1	77.5	4.1	3.9	95.1	7.9, p< 0.05
21	Sad	4.4	3	68.2	4.5	4.3	95.6	11.4, p< 0.05
22	Embarrassed	4.5	3	66.7	4.6	3.6	78.3	3.9, p< 0.05
Total`		4.1	2.6	64.8	4.1	3.7	90.2	3.6, p< 0.05

Table 4. *Comparative characteristics of mean levels of situational anxiety in comparable groups (%).*

Situational anxiety	First visit			7th day			14th day		
	Experimental group	Control group	z,p	Experimental group	Control group	z,p	Experimental group	Control group	z,p
Low level	17,1 (n=77)	22,0 (n=99)	0.5, p> 0.05	28,0 (n=126)	20,8 (n=94)	1.24, p> 0.05	8,8 (n=40)	28,0 (n=126)	3.2, p< 0.01
Middle level	11,3 (n=51)	4,9 (n=22)	1.0, p> 0.05	32,0 (n=144)	10,0 (n=45)	3.7, p < 0.01	72,0 (n=324)	24,0 (n=108)	9.98, p < 0.01
High level	71,6 (n=322)	73,1 (n=329)	0.4, p> 0.05	40,0 (n=180)	69,2 (n=311)	6.5, p < 0.01	19,2 (n=86)	48,0 (n=216)	5.3, p < 0.01
Total	100 (n=450)	100 (n=450)		100 (n=450)	100 (n=450)		100,0 (n=450)	100 (n=450)	

(table 3). There was marked improvement in the quality of daily activity. The quality of daily activities improved by 65.7% in the main group, 52.4% in the control group, and the quality of sleep by 79.5% և 55.4%, respectively.

Trends in the reduction of chronic rhinosinusitis symptoms were expressed in the main group, where Gutanos was added to the complex therapy. No complications or side effects were reported in either group.

There is a reliable connection between the situational and individual anxieties and the symptomatic manifestation of chronic rhinosinusitis (r=+0,8; p=0,01). Depending on the situational anxiety level the patients were divided into 3 groups. It has turned out that after 1month treatment in the main group a high level of situational anxiety was recorded in 19,2% cases, when the index in the control group was 48,0%, whereas low level situational anxiety was 8.8% in the main group and 28,0% (table 4).

Discussion.

The dynamics of the major subjective symptoms in the compared groups showed that in the symptoms of nasal congestion, nasal discharge, facial pain and sense of taste, a stable significant difference was found between the experimental and control groups already during the 4-5th visit.

What appears to be the dynamics of the main objective symptoms (Nasal Mucosal Edema, Nasal mucosa hyperemia) in the compared groups, statistically significant differences between the experimental and control groups emerged at 3-4 visits to the doctor.

The analysis of the disease symptoms after the treatment (SNOT 22 questionnaire was filled in before and after the treatment using 5points scale) showed that in the experimental group, the percentage of symptoms of the disease is significantly less than in control group.

Comparative characteristics of the average levels of situational anxiety in comparable groups showed that situational anxiety was significantly and predominantly lower in the experimental group. The fact that the treatment of rhinosinusitis has a positive effect on the psycho-emotional state of the patient is confirmed by the studies of other authors[16,17,18].

Conclusion.

SNOT-22 was adapted into Armenian, creating a tool for assessing patients with clinically significant sinonasal disorders and for scientific research (Cronbach index = 0.89 and ICC test-retest reliability = 0.87). SNOT-22 was found to be reliable and easy to use.

It can be used to facilitate daily clinical practice to highlight the impact of chronic rhinosinusitis on a patient's quality of life. The use of the herbal preparation "Gutanos" in complex therapy makes it possible to increase the effectiveness of the therapeutic effect and reduce the clinical severity of the disease, anxiety, improve the quality of life of patients compared with the results obtained with the standard treatment regimen for chronic rhinosinusitis.

Competing interests.

The authors declare that they have no competing interests.

Ethics approval and consent to participate.

According to the Ethics Guidelines of the Yerevan State Medical University, ethical approval was not required (IRB Expert Conclusion No. 2/14, 10/23/2014) and no personal identifiers were included.

This work was supported by the Science Committee of RA (Research project № 22YR-3B014).

REFERENCES

1. Adnane C, Adouly T, Oubahmane T, et al. Psychometric Validation of a Moroccan Version of the 22-Item Sino-Nasal Outcome Test. Otolaryngol Head Neck Surg. 2016;4:681.

2. Bhattacharyya N, Gilani S. Prevalence of Potential Adult Chronic Rhinosinusitis Symptoms in the United States. Otolaryngol Head Neck Surg. 2018;159:522-525.

3. C Hopkins, S Gillett, R Slack, et al. Psychometric validity of the 22-item Sinonasal Outcome Test. Clin Otolaryngol. 200;34:447-454.

4. Fokkens WJ, Lund VJ, Mullol J, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2012. Rhinol Suppl. 2012;23:1-298.

5. Guilherme Pilla Caminha; José Tavares de Melo Junior; Claire Hopkins; Emilio Pizzichini; Marcia Margaret Menezes Pizzichini. SNOT-22: psychometric properties and cross-cultural adaptation into the portuguese language spoken in Brazil. Brazilian Journal of Otorhinolaryngology. 2012;78:6.

6. Hamsa N Subramanian, Kenneth B Schechtman, Daniel L Hamilos. A retrospective analysis of treatment outcomes and time to relapse after intensive medical treatment for chronic sinusitis. Am J Rhinol. 2002;16:303-312.

7. Harvey R, Hannan SA, Badia L, et al. Nasal saline irrigations for the symptoms of chronic rhinosinusitis. Cochrane Database Syst Rev. 2007;3:CD006394.
8. Hastan D, Fokkens WJ, Bachert C, et al. Chronic rhinosinusitis in European underestimated disease. A GA²LEN study. Allergy. 2011;66:1216-1223.
9. J Palm, I Steiner, D Abramov-Sommariva, et al. Assessment of efficacy and safety of the herbal medicinal product BNO 1016 in chronic rhinosinusitis. Rhinology. 2017;55:142-151.
10. Joaquim Mullol. Trends on rhinosinusitis diagnosis and treatment. Otolaryngol Pol. 2009;63:3-4.
11. Jund R, Mondigler M, Steindl H, et al. Clinical efficacy of a dry extract of five herbal drugs in acute viral rhinosinusitis. Rhinology. 2012;50:417-426.
12. Kai-Li Liang, Yi-Chang Su, Chen-Chen Tsai, et al. Postoperative care with Chinese herbal medicine or amoxicillin after functional endoscopic sinus surgery: a randomized, double-blind, placebo-controlled study. Am J Rhinol Allergy. 2011;25:170-175.
13. Lachanas VA, Tsea M, Tsiouvaka S, et al. The sino-nasal outcome test (SNOT)-22: validation for Greek patients. Eur Arch Otorhinolaryngol. 2014;271:2723-2728.
14. Laura J Vandelaar, Zi Yang Jiang Alok Saini, William C Yao, et al. Citardi PHQ-9 and SNOT-22: Elucidating the Prevalence of Depression in Chronic Rhinosinusitis. Otolaryngol Head Neck Surg. 2020;162:142-147.
15. Lin Lin, Fei Dai, Guoqiang Ren, et al. Efficacy of lianhuaqingwen granules in the management of chronic rhinosinusitis without nasal polyps. Am J Otolaryngol. 2020;41:102311.
16. Rôzanska-Kudelska M. et al. Quality of life, depression, and anxiety symptoms in patients with chronic rhinosinusitis with polyps treated by endoscopic sinus surgery. Pol Merkur Lekarski. 2012;32:228-231.
17. Kremer B, den Hartog HM, Jolles J. Relationship between allergic rhinitis, disturbed cognitive functions and psychological well-being. Clin Exp Allergy. 2002;32:1310-1315.
18. Camelo-Nunes IC, Solé DJ. Allergic rhinitis: indicators of quality of life. Bras Pneumol. 2010;36:124-133.
19. Alt JA, et al. Sleep quality and disease severity in patients with chronic rhinosinusitis. Laryngoscope. 2013.
20. ICH Topic E6 (R1), Step 5 Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Final approval by CPMP:/Date for coming into operation:
January 1997; Post Step Errata (linguistic minor corrections): 11-30.
21. Rolia F, Cortesi E. Quality of life as a primary end point in oncology. Ann Oncol. 2001;12:3-6.
22. Rong-San Jiang, Shang-Heng Wu, Chen-Chen Tsai, et al. Efficacy of Chinese herbal medicine compared with a macrolide in the treatment of chronic rhinosinusitis without nasal polyps. Am J Rhinol Allergy. 2012;26:293-297.
23. Rudmik L, Smith TL, Schlosser RJ, et al. Productivity costs in patients with refractory chronic rhinosinusitis. Laryngoscope. 2014;124:2007-2012.
24. Santos G, Reyes P, del Castillo R, et al. Cross-cultural adaptation, and adaptation, of the sino-nasal outcome test (SNOT-22) for Spanish-speaking patients. Eur Arch Otorhinolaryngol. 2015:3335-3340.
25. Sarfaraz M Banglawala, Samuel L Oyer, Shivangi Lohia, et al. Olfactory outcomes in chronic rhinosinusitis with nasal polyposis after medical treatments: a systematic review and meta-analysis. Int Forum Allergy Rhinol. 2014;4:986-994.
26. Staquet M, Berzon R, Osoba D, et al. Guidelines for reporting results of qualitquality-of-lifesments in clinical trials. Quality of Life Research. 1996;55:496-502.
27. Vasileios A Lachanas, Malamati Tsea, Stergiani Tsiouvaka, et al. The sino-nasal outcome test (SNOT)-22: validation for Greek patients. Eur Arch Otorhinolaryngology. 2014;271:2723-2728.
28. World Medical Association (WMA): WMA Declaration of Helsinki - Ethical principles for medical research involving human sub jects. Adopted by the 48th WMA General Assembly, Somerset West, October 1996.
29. Yael Shapira Galitz, Doron Halperin, Yosef Bavnik, et al. Sino-Nasal Outcome Test-22: Translation, Cross-cultural Adaptation, and Validation in Hebrew-Speaking Patients. Otolaryngol Head Neck Surg. 2016;154:951-956.

НОВЫЕ ПОДХОДЫ К ОЦЕНКЕ ЭФФЕКТИВНОСТИ РАСТИТЕЛЬНЫХ ПРЕПАРАТОВ, ИСПОЛЬЗУЕМЫХ В СХЕМЕ ЛЕЧЕНИЯ ХРОНИЧЕСКИХ РИНОСИНУСИТОВ, НА ОСНОВЕ ИЗМЕНЕНИЙ ПАРАМЕТРОВ КАЧЕСТВА ЖИЗНИ

Абстракт

Оценка качества жизни является одним из важнейших критериев оценки эффективности лечения в клинических исследованиях. Очень важным при этом является правильный выбор методов оценки и анализа. Оценка качества жизни, связанного со здоровьем, очень важна для оценки эффективности медицинских препаратов. Указанный показатель рассматривается в качестве дополнительного способа оценки эффективности медицинского препарата в клинических исследованиях, нового инструмента для правильного выбора лечения.

Для оценки воздействия препарата «Гутанос» (противовоспалительные, антимикробные назальные капли растительного происхождения) на качество жизни пациентов с хроническим риносинуситом в качестве статистического инструмента нами был использован опросник «SNOT-22». Английская версия опросника «SNOT-22», с учетом рекомендованных этапов, была переведена на армянский язык и адаптирована. Разработанный опросник показал высокую валидность и надежность (Cronbach index = 0.81, ICC = 0.85) и может использоваться как для оценки качества жизни пациентов с клинически значимыми формами патологии синоназальных путей (риносинуситами), так и в клинических исследованиях. Результаты исследования свидетельствуют о надежности опросника «SNOT-22», его простоте в применении и возможности использования с целью упрощения оценки влияния хронических риносинуситов на качество жизни пациентов в клинической практике.

Ключевые слова: качество жизни, опросник SNOT-22, хронические риносинуситы, «Гутанос».