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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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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 computer-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.

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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. მიკროფოტო-სურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სუ-რათის 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.

Содержание:

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COMPARATIVE ANALYSIS OF THE EFFICACIES OF BOTULINOTOXIN A THERAPY AND FRACTIONAL RADIO-FREQUENCY-LIFTING IN THE TREATMENT OF PRIMARY HYPERHYDROSIS

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Abstract.

Hyperhydrosis (HH) is a pathology of eccrine gland which is manifested by excessive sweating on the skin. It has a significant negative impact on an individual's quality of life (QoL). Primary HH is the most common idiopathic condition which is mostly localized. Botulinum toxin A therapy (BTX) treatment is one of the proven, minimally invasive methods for HH treatment; however, minimally invasive fractional RF-lifting with microneedles for primary HH is of great interest of researchers.

The aim of our study was to compare the effectiveness of fractional RF-lifting with microneedles and botulinum toxin-A treatment methods in people with primary HH and to determine the role of these methods in HH management tactics based on the analysis.

Methods: After signing the consent agreement 60 patients with HH participated in the study. 30 patients were selected for BTX (group 1), another 30 participants – for RF-lifting with microneedles (group 2). Target areas of treatment were the armpit, palm, and sole. The assessment of treatment efficacy was performed by the questionnaires of the Dermatology Patient Quality of Life Index (DLQI) and Hyperhidrosis Severity Score (HDSS).

Results: Mean value of DLQI-score before treatment in group 1 was 18.1 ± 4.3 , and in in group 2 - 13.3 ± 5.6 (the difference was significant - p<0.001). After treatment these scores were 8.3 ± 5.5 and 6.6 ± 5.3 , respectively (the difference was not significant - p=0.228). As for intragroup difference of DLQI-scores before and after treatment, they were decreased significantly (p<0.001 for both groups). Moreover, the percentages of the patients with high degree HH were significantly decreased in both groups. However, the difference between the DLQI-scores of groups both before and after treatment was not significant. Both methods proved to be significantly effective for all three locations, especially for the armpit. However, no significant differences were observed when comparing the methods.

Conclusions: The results of the study based on the DLQI-questionnaire indicate that application of both methods improved QoL of HH patients and decreased the degree of severity significantly. Both methods may be applied in the tactics of HH treatment with equal success rates. Additional randomized trials are needed to make evidence-based conclusions.

Key words. Botulinotoxin, Radio-Frequency-Lifting, Hyperhidrosis.

Introduction.

Hyperhydrosis (HH) is the pathology of eccrine gland which is manifested by excessive sweating on the skin. It has a significant negative impact on the quality of life (QoL) and affects about 3% of the general population, mostly in people aged 25-64 [1]. The negative impact is expressed on the social, mental, and emotional components of the daily QoL. According to the modern classification, primary and secondary HH are distinguished. Primary HH is manifested locally on the skin of axillary, palmar, plantar and face; they are not associated with systemic lesions; secondary HH is related with systemic lesions – endocrine and metabolic system disorders, infectious, oncological, vasomotor diseases, nervous system and psychoemotional pathology [2]. However, clinical manifestations of primary and secondary HH vary depending on the family history, age, symptoms, location, and causes [3].

One of the proven methods of the HH treatment is the Botulinotoxin A therapy (BTX). It is protein-based neurotoxin isolated from bacteria "Clostridium botulinum" and characterized by the temporarily suppressive effect of signal pulse transmission [4]. There are proposed several methods to treat HH, but there is no consensus and no clear guidelines, which is of great interest for researchers to discover a new, highly effective, and safe treatment method.

In the case of primary hyperhidrosis, the use of fractional RF-lifting is a new method of treatment.

Based on various studies, the efficacy and safety of fractional RF-lifting have been evaluated for various dermatoses. In the case of primary HH, RF-lifting is a new method of treatment. It is based on a radio-fractional microwave device and characterized by the selective superficial thermal impact on the area between the skin and subcutaneous tissues [5]. However, there was no consensus about the efficacy of RF-lifting and the results of comparative studies of BTX and RF-lifting for the patients with primary HH.

The aim of our study was to compare the effectiveness of fractional RF-lifting with microneedles and botulinum toxin-A treatment methods in people with primary HH and to determine the role of these methods in HH management tactics based on the analysis.

Methods.

The protocol of our cross-sectional follow-up observational study was approved by the Ethics Committee of the Institutional Review Board (Protocol No.31/a, 15/Jul/2020). After signing the consent agreement 60 patients with HH participated in the study. 30 patients were randomly selected for BT (group 1), another 30 participants – for RF-lifting with microneedles (group 2). Target areas of treatment were the axilary, palmar, and plantar. Follow-up period was app. 6 months.

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Table 1. Follow-up data of the values of the degree of HH severity.

The IIII degree of	Group 1 (BTA, n=30)		Group 2 (RFL, n=30)	Group 2 (RFL, n=30)	
The HH degree of severity (HDSS)	before treatment	after treatment	before treatment	after treatment	
1	0 (0.0%)	9 (30.0%)	0 (0.0%)	7 (23.3%)	
2	0 (0.0%)	11 (36.7%)	0 (0.0%)	10 (33.3%)	
3	13 (43.3%)	8 (26.7%)	11 (36.7%)	11 (36.7%)	
4	17 (56.7%)	2 (6.7%)	19 (63.3%)	2 (6.7%)	
Chi2-test, p	33.03 (p<0.001)		30.76 (p<0.001)		
Chi2-test, p between	before treatment - 0.28 (p=0.598)				
groups	after treatment - 0.77 (p=0.856)				

Table 2. The distribution of the answers on each question of DLQI-questionnaire and the interpretation of obtained results in group 1.

D T	Group 1 (BT, n=30)	Group 1 (BT, n=30)			
Pre-Treatment Question #	Not at all or	A little –	A lot –	Very much –	
Question #	Not relevant – score 0	score 1	score 2	score 3	
Q1	5 (16.7%)	13 (43.3%)	11 (36.7%)	1 (3.3%)	
Q2	1 (3.3%)	3 (10.0%)	17 (56.7%)	9 (30.0%)	
Q3	8 (26.7%)	3 (10.0%)	19 (63.3%)	0 (0.0%)	
Q4	0 (0.0%)	0 (0.0%)	19 (63.3%)	11 (36.7%)	
Q5	1 (3.3%)	4 (13.4%)	19 (63.3%)	6 (20.0%)	
Q6	1 (3.3%)	5 (16.7%)	19 (63.3%)	5 (16.7%)	
Q7	5 (16.7%)	4 (13.4%)	10 (33.3%)	11 (36.7%)	
Q8	0 (0.0%)	5 (16.7%)	19 (63.3%)	6 (20.0%)	
Q9	4 (13.4%)	8 (26.7%)	14 (46.7%)	4 (13.4%)	
Q10	5 (16.7%)	6 (20.0%)	18 (60.0%)	1 (3.3%)	
Post-Treatment	Not at all or	A little –	A lot –	Very much –	
Question #	Not relevant – score 0	score 1	score 2	score 3	
Q1	29 (96.7%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	
Q2	29 (96.7%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	
Q3	5 (16.7%)	15 (50.0%)	9 (10.0%)	1 (3.3%)	
Q4	4 (13.4%)	14 (46.7%)	10 (33.3%)	2 (6.7%)	
Q5	6 (20.0%)	12 (40.0%)	12 (40.0%)	0 (0.0%)	
Q6	6 (20.0%)	12 (40.0%)	12 (40.0%)	0 (0.0%)	
Q7	12 (40.0%)	9 (10.0%)	5 (16.7%)	4 (13.4%)	
Q8	6 (20.0%)	14 (46.7%)	9 (10.0%)	1 (3.3%)	
Q9	10 (33.3%)	12 (40.0%)	8 (26.7%)	0 (0.0%)	
Q10	14 (46.7%)	10 (33.3%)	5 (16.7%)	1 (3.3%)	
Sum of Scores	Interpretation of DLQI Score	26	Pre-Treatment	Post-Treatment	
interpretation of DEQL Scores			n (%)	n (%)	
0-1	No effect at all on patient's life		0 (0 0%)	2 (6.7%)	

Sum of Scores	Intermustation of DLOI Seems	Pre-Treatment	Post-Treatment
	Interpretation of DLQI Scores	n (%)	n (%)
0-1	No effect at all on patient's life	0 (0.0%)	2 (6.7%)
2-5	Small effect on patient's life	0 (0.0%)	10 (33.3%)
6-10	Moderate effect on patient's life	2 (6.7%)	8 (26.7%)
11-20	Very large effect on patient's life	17 (56.7%)	10 (33.3%)
21-30	Extremely large effect on patient's life	11 (36.7%)	0 (0.0%)

Chi2-test = 28.41, df=4, p<0.001

Assignment of the groups:

Group 1A – Localization armpit in group 1 (Botulinotoxin A therapy, n=10); Group 1P – Localization Palm in group 1 (n=10); Group 1S – Localization Sole in group 1 (n=10).

Group 2A – Localization armpit in group 2 (RF therapy, n=10); Group 2P – Localization Palm in group 2 (n=10); Group 2S – Localization Sole in group 2 (n=10).

The assessment of treatment efficacy performed by the questionnaires of the determination of the index of Quality of life of Dermatologic Patients (DLQI) and degree of the severity

of the hyperhydrosis (HDSS). DLQI-questionnaire consists of 10 simple proven questions, applied for up to 40 various diseases in 80 countries and interpreted in up to 110 languages. Georgian version is adapted. DLQI-questionnaire consists of several components: the impact of skin diseases on the QoL, functional and social characteristics, relation, and emotional components [6]. The scale of HH degree of severity was suggested by HH International Society. It requires the self-assessment of the HH degree based on 4 simple question. It gives the opportunity to evaluate the degree of severity [7].

Table 3. The distribution of the answers on each question of DLQI-questionnaire and the interpretation of obtained results in group 2.

Pre-Treatment	ჯგუფი 2 (RFL, n=30)	ჯგუფი 2 (RFL, n=30)				
Question #	Not at all or	A little –	A lot –	Very much –		
Question #	Not relevant – score 0	score 1	score 2	score 3		
Q1	8 (26.7%)	16 (53.3%)	3 (10.0%)	3 (10.0%)		
Q2	0 (0.0%)	6 (20.0%)	19 (63.3%)	5 (16.7%)		
Q3	7 (26.7%)	4 (13.4%)	14 (46.7%)	5 (16.7%)		
Q4	0 (0.0%)	4 (13.4%)	21 (70.0%)	5 (16.7%)		
Q5	1 (3.3%)	10 (33.3%)	14 (46.7%)	5 (16.7%)		
Q6	5 (16.7%)	6 (20.0%)	14 (46.7%)	5 (16.7%)		
Q7	26 (86.7%)	0 (0.0%)	4 (13.4%)	0 (0.0%)		
Q8	16 (53.3%)	0 (0.0%)	13 (43.3%)	1 (3.3%)		
Q9	14 (46.7%)	3 (10.0%)	12 (40.0%)	1 (3.3%)		
Q10	13 (43.3%)	4 (13.4%)	12 (40.0%)	1 (3.3%)		
Post-Treatment	Not at all or	A little –	A lot –	Very much –		
Question #	Not relevant – score 0	score 1	score 2	score 3		
Q1	20 (66.7%)	8 (26.7%)	2 (6.7%)	0 (0.0%)		
Q2	6 (6.7%)	20 (66.7%)	3 (10.0%)	1 (3.3%)		
Q3	13 (43.3%)	11 (36.7%)	5 (16.7%)	1 (3.3%)		
Q4	10 (33.3%)	12 (40.0%)	8 (27.7%)	0 (0.0%)		
Q5	9 (30.0%)	16 (53.3%)	4 (13.3%)	1 (3.3%)		
Q6	11 (36.7%)	15 (50.0%)	4 (13.3%)	1 (3.3%)		
Q7	16 (53.3%)	8 (26.7%)	5 (16.7%)	1 (3.3%)		
Q8	9 (30.0%)	17 (56.7%)	3 (10.0%)	1 (3.3%)		
Q9	17 (56.7%)	9 (30.0%)	3 (10.0%)	1 (3.3%)		
Q10	19 (63.3%)	7 (23.3%)	4 (13.3%)	0 (0.0%)		
Cum of Coopea	Intermutation of DI OI Second		Pre-Treatment	Post-Treatment		
Sum of Scores	Interpretation of DLQI Scor	es	n (%)	n (%)		
0-1	No effect at all on patient's life	;	0 (0.0%)	8 (16.7%)		
2-5	Small effect on patient's life		2 (6.7%)	3 (10.0%)		

C C C	Interpretation of DLQI Scores		
Sum of Scores		n (%)	n (%)
0-1	No effect at all on patient's life	0 (0.0%)	8 (16.7%)
2-5	Small effect on patient's life	2 (6.7%)	3 (10.0%)
6-10	Moderate effect on patient's life	10 (33.3%)	15 (50.0%)
11-20	Very large effect on patient's life	16 (53.3%)	3 (10.0%)
21-30	Extremely large effect on patient's life	2 (6.7%)	1 (3.3%)

Chi2-test = 18.43, df=4, p=0.001

Table 4a. Mean pre- and post-treatment mean values of DLQI scores in group 1 divided according to the localization.

Study Period	Group 1A	Group 1P	Group 1S	
	DLQI scores, Mean ± SD	DLQI scores, Mean ± SD	DLQI scores, Mean ± SD	
Pre-treatment	19.3 ± 4.1 *	18.7 ± 2.8 **	16.3 ± 5.5 ***	
t-test, p between groups	1A-1B - 0.38, p=0.707 (NS); 1A-1	C - 2.36, p=0.184 (NS); 1B-1C - 1.2	3, p=0.235 (NS)	
Post-treatment	6.2 ± 4.6	11.5 ± 5.4	8.8 ± 5.5	
t-test, p between groups	1A-1B - 2.36, p= 0.030 ; 1A-1C - 1.15, p=0.267 (NS); 1B-1C - 1.11, p=0.283 (NS)			
Therapy effect	13.1 ± 5.6	7.2 ± 5.3	7.5 ± 5.3	
t-test, p between groups	1A-1B - 2.42, p=0.026 ; 1A-1C - 2.30, p=0.034 ; 1B-1C - 0.13, p=0.901 (NS)			

^{*} pre- and post-treatment **DLQI** scores in group 1A were differed significantly t=6.723, p<0.001

Inclusion criteria:

- Primary HH clinically diagnosed by the physician-dermatologist.
 - Age 18-50 years.
 - Severity degree III and IV.
 - Signing the consent agreement.

Exclusion criteria:

•Secondary HH clinically diagnosed by the physician-dermatologist.

- Age less than 18 and more than 50 years.
- Severity degree I and II.
- Rejection signing the consent agreement.

Statistics.

Study data statistically treated by the soft SPSS v.22.0. Nominal variables are presented as Mean \pm standard deviation (SD). Categorical variables are presented as n and percentages. The comparison of the nominal variables between the groups was performed by two-sided t-test. The comparison of the

^{**} pre- and post-treatment **DLQI** scores in group 1P were differed significantly t=3.743, p=0.002

^{***} pre- and post-treatment **DLQI** scores in group 1S were differed significantly t=3.049, p=0.007

Table 4b. Mean pre- and post-treatment mean values of DLQI scores in group 2 divided according to the localization.

Study Period	Group 2A	Group 2P	Group 2S	
	DLQI scores, Mean ± SD	DLQI scores, Mean ± SD	DLQI scores, Mean ± SD	
Pre-treatment	15.0 ± 6.3 *	13.5 ± 4.8 **	11.3 ± 5.6 ***	
t-test, p between groups	1A-1B - 0.60, p=0.557 (NS); 1A-1C - 1.39, p=0.182 (NS); 1B-1C - 0.94, p=0.358 (NS)			
Post-treatment	6.8 ± 2.9	6.1 ± 5.2	6.4 ± 4.9	
t-test, p between groups	1A-1B - 0.37, p=0.714 (NS); 1A-1C - 0.22, p=0.827 (NS); 1B-1C - 0.13, p=0.896 (NS)			
Therapy effect	8.2 ± 5.8	7.4 ± 3.8	4.9 ± 3.4	
t-test, p between groups	1A-1B - 0.37, p=0.720 (NS); 1A-1C - 1.55, p=0.138 (NS); 1B-1C - 1.55, p=0.138 (NS)			

^{*} pre- and post-treatment **DLQI** scores in group 2A were differed significantly t=3.739, p=0.002

categorical variables between the groups was performed by two-sided Chi2-test. The criterion of the rejection of null hypothesis was p<0.05.

Results.

The follow-up data of the values of the degree of HH severity evaluated by HDSS-questionnaire are given in 1.

The data from 1 shows that percentages of the patients with high degree of HH severity decreased significantly. The quantity of patients with III and IV degree in group 1 (BT) was decreased from 30 (100%) to 10 (33.3%); the quantity of patients with III and IV degree in group 2 (RF) was decreased from 30 (100%) to 13 (42.3%); however, the difference between groups was not significant.

The distribution of the answers to each question of DLQIquestionnaire in groups are given in s 2 and 3.

The results from 2 show that the percentage of patients with good QoL was increased significantly after treatment (Chi2=28.41, p<0.001). The mean value of DLQI-score before treatment was 18.1 ± 4.3 ; after treatment - 8.3 ± 5.5 . The decrease of this value was significant (p<0.001).

The results from 2 show that the percentage of patients with good QoL was increased significantly after treatment (Chi2=18.43, p<0.001). The mean value of DLQI-score before treatment was 13.3 ± 5.6 ; after treatment - 6.6 ± 5.3 . The decrease of this value was significant (p<0.001).

The difference of mean DLQI-scores between groups before treatment was significant - p<0.001. After treatment the difference became non-significant - p=0.228.

The distribution of the percentages of DLQI-score ranges between groups indicated before treatment was not significant (Chi2=5.93, p=0.115, NS); after treatment the distribution became significant (Chi2=14.27, p=0.007).

The results obtained by DLQI-questionnaire according localization area are given in s 4a and 4b.

The comparison of obtained results between groups shows that both before and after treatment DLQI-scores were not significant. In contrary, the DLQI scores for palm was significant before treatment (p=0.008) as well as after treatment (p=0.035); but the efficacies was not differed significantly.

Discussion.

Hyperhidrosis (HH) refers to a condition involving dysfunction within the central nervous system, characterized by an abnormal increase in sweating due to the disruption of sweat secretion regulation at the central level [8]. The most excessive areas

during HH are axilary, palmar, plantar and face [9]. HH has a particularly negative and stressful impact on the QoL of patients [10]. Due to the severe social and economic burden of disproportionate sweating, existing treatment methods are still insufficient to meet the expectations of patients. Therefore, researchers continue to search for new therapy methods that combine the most desirable features, such as: relief of symptoms, elimination of side effects, convenient use, and long-term effects [11]. Local treatment methods are the first-line therapies, followed by a wide range of alternative methods, such as oral agents, minimally invasive medical approaches, and surgical techniques [12,13,14]. Widespread implementation of various methods in the treatment of axillary HH is due to the presence of such medical devices as microwave thermolysis, radiofrequency, ultrasound, and laser therapies. Their fundamental therapeutic effect is based on mechanical disruption of eccrine sweat glands, which is confirmed by further histological analysis. Nevertheless, the use of medical devices is not free from side effects and, more importantly, is associated with significant costs [15]. Nevertheless, it is necessary and recommended to change the lifestyle, which means avoiding such provoking factors as: spicy food, alcohol, wearing occlusive clothes and shoes [16]. BTX treatment is known to be a well-studied treatment method for local HH. Based on various studies, it is a safe and effective treatment method that has a long-term effect compared to the local therapy. BTX is most effective for the treatment of axial HH. It is also recommended for the treatment of palm and sole HH. Its effectiveness lasts from 6 to 9 months, depending on the dose, procedure technique and individual characteristics [17]. BTX improves the QoL which is very low due to HH. Compared to other interventions, this treatment has a high safety rate, which once again confirms its superiority [18].

The mechanism of BTX action is aimed at blocking the acetylcholine released from the presynaptic nerve endings of the central nervous system, thereby inhibiting the stimulation of the eccrine sweat gland. The advantage of BTX is its effectiveness, safety, and tolerance, while the main drawback is the high cost, the need for repeated procedures and the high risk of potential resistance to antibodies [17].

Fractional RF-lifting with microneedles is an innovation that directs radio wave energy into the dermis and subcutaneous tissue through isolated microneedles, causing thermal effects in the sweat glands and surrounding tissues. The effectiveness of fractional RF-lifting with microneedles lasts up to one year, depending on the number of procedures, as well as energy

^{**} pre- and post-treatment **DLQI** scores in group 2P were differed significantly t=3.307, p=0.004

^{***} pre- and post-treatment **DLQI** scores in group 2S were differed significantly t=2.041, p=0.056 (NS)

frequency and individual variability. The main advantage of fractional RF-lifting with microneedles is its minimal invasiveness, low risk of complications and long-term results. The main disadvantage is its low efficiency, high level of pain and longer regeneration time compared to BTX. As mentioned above, it requires a repeat procedure, and the time interval is shorter in patients with a high mass index [19-20].

As mentioned above, there are several treatment options, but there are no consensus and clear guidelines for the treatment of these patients [21]. Therefore, researchers continue to search for new, highly effective therapy methods that combine the most desirable features, such as complete relief of symptoms, elimination of side effects, convenient use, and long-lasting effects. It should be noted that there is little information in scientific literature about the comparison of these methods mentioned above in our study.

According to the data of our study two methods of HH treatment were assessed by the DLQI-scores and HDSS-score. The results of the study showed a significant decrease in DLQI scores for both groups after treatment (p<0.001). In addition, the study showed a significant reduction in the potential rate of patients with severe HH in both groups. Study results showed that DLQI-scores were significantly decreased after treatment in both groups (p<0.001). In addition, the study showed a significant reduction in the rate of patients with potential severe HH in both groups. However, the difference between groups before and after treatment was not significant. It is indicated that BTX and RF-lifting were effective to reduce the degree of HH severity and to improve the QoL of patients.

It should also be noted about the limitation of our study. The small number of examined patients and the lack of long-term results, which does not allow us to make solid and evidence-based conclusions accep to medicine. For this, randomized, large-scale and long-term outcome-oriented studies are needed.

Conclusion.

The results of our study based on the DLQI-questionnaire indicate that application of BTX and RF-lifting improved QoL of HH patients and decreased the degree of severity significantly. At this stage, we can conclude that both methods can be used with equal success for the treatment of primary HH. Additional randomized trials are needed to make evidence-based conclusions.

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აბსტრაქტი: ჰიპერჰიდროზი ეკრინული ჯირკვლის პათოლოგიაა, რომელიც კანზე ვლინდება ოფლის ჭარბი გამოყოფით. იგი მნიშვნელოვან უარყოფით გავლენას ახდენს ინდივიდის ცხოვრების ხარისხზე. პირველადი ჰიპერჰიდროზი ყველაზე გავრცელებული იდიოპათიური მდგომარეობაა, რომელიც ძირითადად ვლინდება ლოკალურად. **პიპერჰიდროზის** მკურნალობაში ერთ-ერთი აპრობირებული, მცირედ ინვაზიური მეთოდია ბოტულინოტოქსინით მკურნალობა, თუმცა მკვლევართა დიდ ინტერესს წარმოადგენს მცირედ ინვაზიური ფრაქციული RFლიფტინგი მიკრონემსებით მკურნალობა პირველადი ჰიპერჰიდროზის დროს.

კვლევის მიზანს: წარმოადგენდა პირველადი ჰიპერჰიდროზით დაავადებულ პირებში, ფრაქციული RF-ლიფტინგიმიკრონემსებით და ბოტულინოტოქსინი -A მკურნალობის მეთოდების ეფექტურობის შედარებითი ანალიზი და ანალიზის საფუძველზე ამ მეთოდების როლის განსაზღვრა ჰიპერჰიდროზის მართვის ტაქტიკაში.

მეთოდები: კვლევაში მონაწილეობა მიიღო 60 პაციენტმა. მათგან 30 პაციენტში ჩატარებულ იქნა ბოტულინოტოქსინი - A ინექცია (ჯგუფი 1), ხოლო დანარჩენ 30 პაციენტში (ჯგუფი 2) კი - ფრაქციული RF-ლიფტინგი მიკრონემსებით. სამიზნე მიდამოებს წარმოადგენდა იღლიის, ხელისა და ფეხის გულების

მკურნალობის მეთოდების ეფექტურობის მიდამო. შეფასეზა გთხდა დერმატოლოგიურ პაციენტთა ხარისხის ცხოვრების ინდექსის განმსაზღვრელი კითხვარისა (DLQI) <u> </u>შიპერჰიდროზით და დაავადებულთა სიმძიმის ხარისხის განმსაზღვრელი კითხვარის (HDSS) მეშვეობით.

შედეგები: ჯგუფში 1 მკურნალობამდე შეფასებული DLQI-ის საშუალო მაჩვენებელმა შეადგინა 18.1 ± 4.3, ხოლო ჯგუფში $2 - 13.3 \pm 5.6$ (ჯგუფებს შორის განსხვავება იყო სარწმუნო - p<0.001). მკურნალობის შემდეგ ამ მაჩვენებლებმა შესაბამისად შეადგინეს - ჯგუფში 1 - 8.3 ± 5.5, ჯგუფში 2 - 6.6 ± 5.3 (ჯგუფებს შორის განსხვავება აღარ გამოდგა სარწმუნო - p=0.228). რაც შეეხება მკურნალობამდელი და მკურნალობის მაჩვენებლების შემდგომი შედარებას ჯგუფების შიგნით, ისინი სარწმუნოდ დაქვეითდნენ (p<0.001 ამასთან ორივე ჯგუფში შემთხვევაში). სარწმუნოდ დაქვეითდა სიმძიმის მაღალი ხარისხის მქონე პაციენტების პროცენტული მაჩვენებლები, თუმცა ჯგუფებს შორის განსხვავება როგორც მკურნალობამდე, ისე მკურნალობის შემდეგ არ იყო სარწმუნო.

დასკვნა: დერმატოლოგიურ პაციენტთა ცხოვრების ხარისხის ინდექსის განმსაზღვრელი კითხვარზე **ჰიპერჰიდროზის** დაყრდნობით მეთოდების ეფექტურობის კვლევის შედეგები უჩვენებს, რომ მათი გამოყენებით სარწმუნოდ უმჯობესდება ცხოვრების ხარისხი და მნიშვნელოვნად გაუმჯობესდა სიმძიმის ხარისხი. მეთოდი თანაბარი წარმატებით ორივე შესაძლოა გამოყენებულ იქნას პირველადი ჰიპერჰიდროზის მკურნალობისათვის.

ფაქტებს დაფუძვნებული დასკვნების გამოსატანად საჭიროებს დამატებით რანდომიზებულ კვლევას.