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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 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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CHANGES IN LOWER LIMB FUNCTIONAL ACTIVITY AND TREATMENT OUTCOMES IN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE FOLLOWING THE APPLICATION OF STANDARD AND MODIFIED TREATMENT PROTOCOLS. A COMPARATIVE ANALYSIS

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Abstract.

Introduction: Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality worldwide. Peripheral arterial disease (PAD) is a dangerous manifestation of ASCVD, often leading to amputations, cardiovascular complications, and mortality. The effectiveness of revascularization is not always predictable, necessitating the refinement of treatment and monitoring approaches.

Aim of the study: Comparative assessment of the effectiveness of standard and modified (adjuvant-supplemented) postoperative treatment protocols, based on the analysis of lower limb functional activity (Fontaine classification) and quality of life indicators (MOS SF-36) in patients with PAD.

Materials and Methods: The study involved 114 patients divided into two groups: Group I (n=58) received standard post-revascularization management, Group II (n=56) received modified management with adjuvant neurometabolic and endothelioprotective therapy. All patients were assessed for lower limb functional activity (Fontaine classification) at the study baseline as well at 1, 3 and 12 months after surgery. The quality of life (MOS SF-36) scoring was performed at the study baseline as well at 3 and 12 months after surgery.

Results: Assessments performed 3 and 12 months after surgery showed that patients receiving modified management maintained significantly better functional activity and higher quality of life scores compared to the standard treatment group. In the standard treatment group, a trend of regression was observed at 12 months, whereas the modified therapy group patients cohort demonstrated the maintenance of the positive trend. Statistical analysis confirmed a strong positive association between the modified treatment protocol and superior long-term outcomes.

Conclusion: The addition of neurometabolic and endothelioprotective adjuvant therapy to standard postoperative care improves lower limb functional activity and quality of life for up to 12 months. This approach may complement current clinical guidelines for PAD management.

Key words. Peripheral arterial disease, occlusion, stenosis, compensated blood flow, postoperative management, Fontaine classification, limb functional activity, MOS SF-36, quality of life.

Introduction.

Atherosclerotic cardiovascular disease (ASCVD) remains the leading cause of morbidity and mortality worldwide. However, peripheral artery disease (PAD) – a common yet frequently underrecognized manifestation of ASCVD – also presents with significant rates of illness and death. According to the Global Burden of Disease study, the number of registered PAD cases worldwide exceeded 236 million as of 2019 [1-5]. PAD is currently considered one of the most severe forms of ASCVD and represents a common cause of amputations, cardiovascular disability, and mortality.

Lesions in the arteries of the lower extremities may follow an asymptomatic course or manifest as intermittent claudication or chronic limb-threatening ischemia [6-9].

The results of numerous studies have confirmed that duplex ultrasonography – as a high-precision, non-invasive, and cost-effective first-line imaging modality – is a reliable method for diagnosing and classifying the severity of PAD. Its role is particularly valuable in evaluating patients with contraindications to radiation or contrast agents [8], as well as in guiding revascularization strategy (endovascular versus surgical), informing decisions regarding invasive interventions, and, most importantly, in the long-term surveillance of bypass grafts and stented segments for detecting clinical progression [4].

At the same time, revascularization, even as an accepted primary treatment modality, cannot be considered a process with entirely predictable efficacy and freedom from complications.

In a significant proportion of patients, even after a technically successful intervention, sufficient regression of limb ischemia is not observed. Without appropriate monitoring, risk factor control, regular surveillance of comorbidities, and systematic management of the postoperative period, significant long-term improvement in quality of life not always can be achieved.

Recent data demonstrate that a substantial proportion of patients with PAD do not receive evidence-based treatment, resulting in an accelerated natural course of the disease and an increased frequency of complications. The effective management of patients with PAD requires a systematic approach encompassing diagnosis, surgical interventions, and conservative therapy [1].

All the above circumstances necessitate the review, improvement, and optimization of the methodology for diagnosing, treating, and monitoring patients with PAD.

The Fontaine classification is considered one of the most important systems for assessing the severity of peripheral arterial occlusive disease. This classification is based solely on the presence of clinical symptoms, which allows for the division of the disease into four main stages, ranging from asymptomatic to severe ischemic damage to the limb [2].

Aim of the Study.

The aim of this study is the comparative assessment of the effectiveness of standard and modified (adjuvant-supplemented)

postoperative treatment protocols, based on the analysis of lower limb functional activity (Fontaine classification) and quality of life indicators (MOS SF-36) in patients with PAD.

Materials and Methods.

The prospective study material consists of clinical data from patients aged 31-85 (average 60.6 ± 14.8) diagnosed with PAD and critical limb ischemia (CLI), as well as data from their periodic follow-up examinations conducted 1, 3, and 12 months after surgery, in accordance with PAD management guidelines [4,5].

The study was conducted in accordance with the ethical standards of the Helsinki Declaration (2013) and approved by the Ethics Committee of the National Institute of Health of the Republic of Armenia. Written informed consent was obtained from all participants prior to inclusion. All diagnostic measures, surgical revascularizations, and postoperative management were carried out at the "Best Life" Medical Center during 2022-2024. Patient recruitment was performed based on the principle of consecutive sampling.

Inclusion Criteria:

- Age over 45.
- Diagnosis of symptomatic PAD with critical limb ischemia (Fontaine Stage III or IV).
- Successful endovascular or surgical revascularization procedure.
- Informed consent for inclusion in the study.

Exclusion Criteria:

- Presence of severe, uncontrolled psychiatric disorders (e.g., schizophrenia, bipolar disorder).
- Intake of the study's adjuvant medications within the last 6 months prior to enrollment.
- Life expectancy of less than 12 months due to non-vascular comorbidities.

Clinical Groups:

114 patients meeting the study's criteria were included and prospectively followed. Patients were divided into 2 interventional groups:

- **Group I (Standard):** Consisted of 58 patients (31 men (53.4%), 27 women (46.6%)) whose postoperative management followed standard guideline-based care, including antiplatelet/ anticoagulant therapy and risk factor control.
- **Group II (Modified):** Consisted of 56 patients (30 men (53.6%), 26 women (46.4%)) whose postoperative management included standard care plus a defined regimen of adjuvant neurometabolic and endothelioprotective therapy.

Division into Clinical Subgroups:

Based on the anatomical level of the primary revascularization procedure, patient groups were divided into two subgroups:

- **Subgroup A:** Patients (n=67, 58.8%) who underwent revascularization without a primary intervention on the femoral segment (e.g., isolated below-the-knee or tibial interventions).
- **Subgroup B:** Patients (n=47, 41.2%) who underwent revascularization with an intervention component on the femoral segment.

Research Methods and Outcome Measures.

Fontaine Classification: The clinical stage of PAD was assessed at each visit using the Fontaine classification, a symptom-based system that categorizes disease severity from Stage I (asymptomatic) to Stage IV (tissue loss) [2]. The lower limb functional activity (Fontaine classification) at the study baseline as well at 1, 3 and 12 months after surgery.

Quality of Life Assessment: Health-related quality of life was assessed using the Medical Outcomes Study 36-Item Short Form Health Survey (MOS SF-36). The survey provides scores on physical and mental health components, with higher scores indicating better health status. It was administered at baseline and follow-up visits [6]. The quality of life (MOS SF-36) scoring was performed at the study baseline as well at 3 and 12 months after surgery.

Treatment Protocols:

- **Group I (Standard Management):** Guideline-directed medical therapy including antiplatelet agents, statins, and management of comorbid diseases as per standard protocols.
- **Group II (Modified Management):** Received all components of Group I therapy plus the following adjuvant regimen for 12 months:
- **1st stage – duration 3 months after operation:**

1. Cilostazol 100 mg daily or Pentoxifylline 400 mg three times daily if cilostazol is contraindicated.
2. Nucleo CMP (cytidine monophosphate (CMP) and uridine diphosphate (UDP) i.m for a 6-day course, followed by oral administration of the drug: 1 capsule twice daily independent of meals.
3. Vitamin C 500-1000 mg/day 2.5-3 mo.

2nd stage – duration 2.5-3 months after 1st stage:

1. Selenium 100-200 mcg/day 2.5-3 mo.
2. Alpha-lipoic acid 600 mg/day 1.5-2 mo.
3. Coenzyme Q10 100-200 mg/day.
4. Hydroxocobalamin (B12) Daily PO 100 mg 2 mo.

3rd stage – duration 3 months after 2nd stage:

1. Nucleo CMP (cytidine monophosphate (CMP) and uridine diphosphate (UDP)) i.m for a 6-day course, followed by oral administration of the drug: 1 capsule twice daily independent of meals.
2. Vitamin C 500-1000 mg/day 2.5-3 mo.

4th stage – duration 2.5-3 months after 4th stage:

1. Selenium 100-200 mcg/day 2.5-3 mo.
2. Alpha-lipoic acid 600 mg/day 1.5-2 mo.
3. Coenzyme Q10 100-200 mg/day.
4. Hydroxocobalamin (B12) Daily PO 100 mg 2 mo.

Statistical Analysis: Data are presented as mean ± standard deviation or counts (percentages). Intragroup comparisons across time points (e.g., baseline vs. 12 months) were performed using paired Student's t-tests for continuous data (SF-36) and chi-square tests for categorical data (Fontaine stage). Intergroup comparisons (Group I vs. Group II at specific time points) were performed using independent samples t-tests and chi-square tests. The Relative Difference (RD) was calculated to express the magnitude of change. A p-value of <0.05 was considered statistically significant. All analyses were performed using SPSS version 23 (IBM Corp.).

Results.

Quality of Life Indicators (MOS SF-36).

Group I (Standard Management):

In Subgroup A, the SF-36 score improved significantly from 85.8 ± 12.7 at baseline to a lower value (indicating better perceived health) at 3 months ($p<0.0001$). However, by 12 months, the score had significantly worsened from the 3-month value ($p=0.007$), though it remained better than baseline ($p=0.030$). This pattern suggests initial improvement followed by partial regression. In Subgroup B, a significant improvement was seen at 3 months ($p<0.0001$), which was largely maintained at 12 months, with scores still significantly better than baseline ($p<0.0001$).

Group II (Modified Management):

In both subgroups, a profound and significant improvement in SF-36 scores was observed at 3 months ($p<0.0001$). Crucially, in Subgroup A, this improvement was not only maintained but further increased at 12 months compared to the 3-month value ($p<0.0001$). In Subgroup B, the dramatic improvement seen at 3 months was fully sustained at 12 months, with no significant regression ($p=0.055$ for 3 vs. 12-month comparison).

Figures 1 and 2 visually represent these SF-36 score trends for Group I and Group II, respectively.

Intergroup Comparison (Group I vs. Group II):

While baseline scores were similar, by 12 months, Group II (Modified) demonstrated significantly superior SF-36 scores compared to Group I in both Subgroup A ($p<0.0001$) and Subgroup B ($p<0.0001$). The magnitude of intergroup difference was markedly larger at 12 months than at 3 months, highlighting the sustained benefit of the adjuvant therapy.

As can be seen from the presented data, a trend towards improvement in QoL indicators was observed three months after the intervention. However, studies conducted twelve months after surgery revealed regression in the shifts observed in Subgroup A of the first clinical group. At the same time, no deterioration in the QoL indicator was observed among patients of the second clinical group. On the contrary, twelve months after surgery, a reliable trend of decreasing MOS Score was maintained in the second clinical group. In Subgroup B of the first clinical group, the level of this indicator, although not undergoing regression, did not maintain a pronounced downward trend, indicating a "cessation of the improvement trend" in quality of life in that cohort. Regarding the inter-subgroup comparison of dynamic

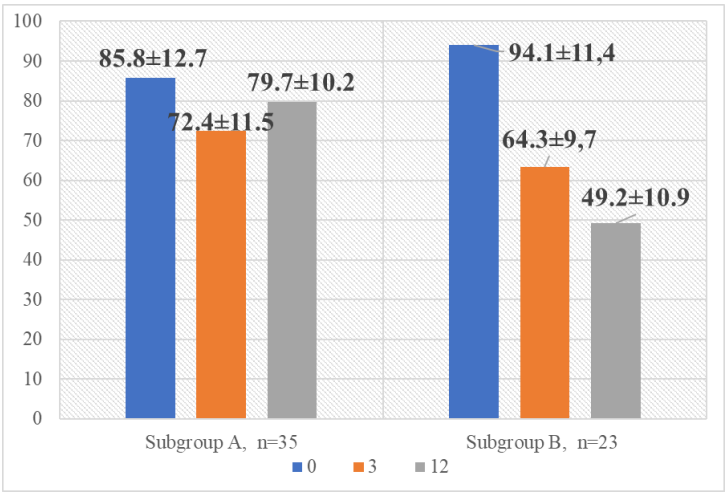

Figure 1. *SF-36 score trends for Group I.*

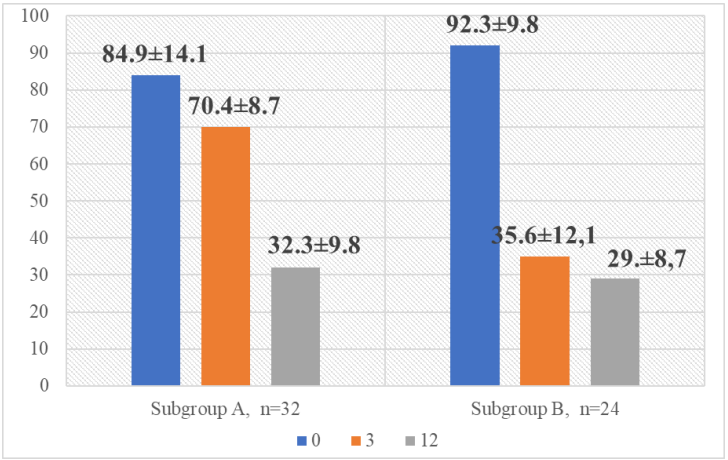

Figure 2. *SF-36 score trends for Group II.*

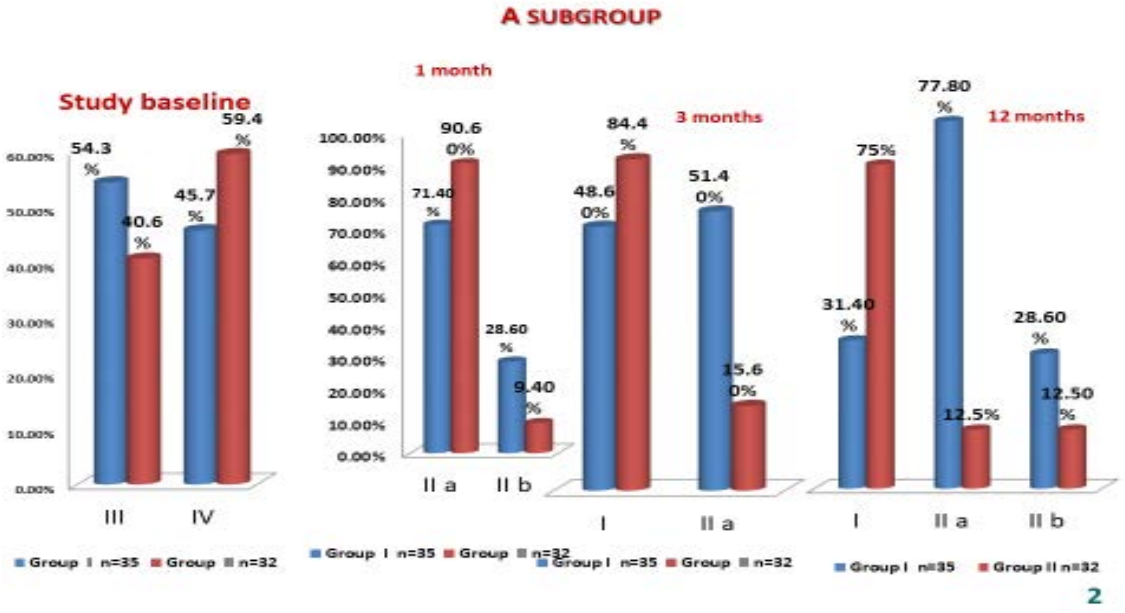

Figure 3. *The dynamic shift in Fontaine stages (Subgroup A).*

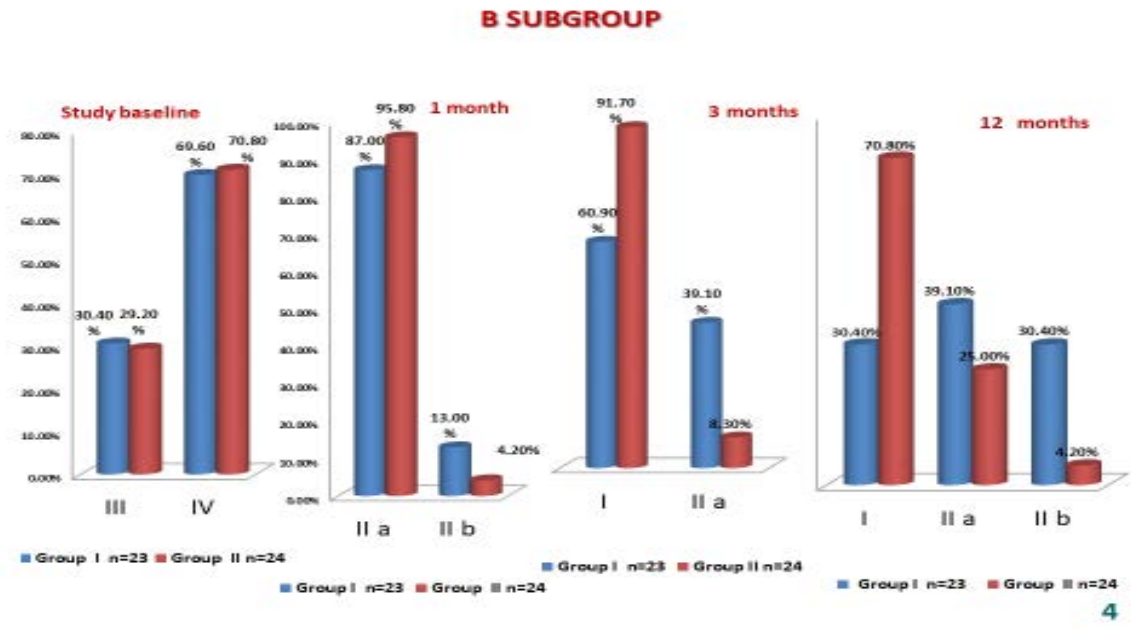

Figure 4. *The dynamic shift in Fontaine stages (Subgroup B).*

changes, the shifts in QoL indicators were more pronounced in Subgroup B of both groups. The obtained results of QoL measurement confirm the more pronounced effectiveness of modified therapy for patients in this cohort.

Limb Functional Activity (Fontaine Classification).

Subgroup A (Non-Femoral Intervention):

At 1 month post-op, most patients in both groups improved to Fontaine Stage IIa/IIb. By 12 months, Group II (Modified) maintained a significantly higher proportion of patients in the better functional stages (Stage I/IIa) compared to Group I (Standard), which showed a shift back towards more severe stages (Stage IIb). Statistical analysis confirmed a strong association between treatment group and Fontaine stage distribution at 3 and 12 months (p=0.002 and p=0.002, respectively).

Subgroup B (Femoral Segment Intervention):

Similar trends were observed. While both groups showed excellent early improvement, the long-term durability differed. At 12 months, Group II (Modified) had a significantly greater proportion of patients remaining in Fontaine Stage I compared to Group I (Standard) (p=0.010). Group I exhibited a clear trend toward functional regression.

Table 1. *Intergroup Comparison of Quality-of-Life Indicators (Statistical Data).*

INDICATOR	SUBGROUP	STATISTICAL INDICATOR	TIME POINT COMPARISONS
MOS SF-36	**A**	**t-value**	**-0.28 (0-0 mo)** **-0.82 (3-3 mo)** **-19.36 (12-12 mo)**
		95%CI	**[-7.301 - 5.501] (0-0 mo)** **[-6.864 - 2.864] (3-3 mo)** **[-52.290 - -42.510] (12-12 mo)**
		p-value	**.780 (0-0 mo)** **.415 (3-3 mo)** **<.0001 (12-12 mo)**
		Abs. diff., %	**1.05 (0-0 mo)** **2.76 (3-3 mo)** **-47.4 (12-12 mo)**
	B	**t-value**	**0.58 (0-0 mo)** **-8.95 (3-3 mo)** **-6.83 (12-12 mo)**
		95%CI	**[-8.037 - 4.437] (0-0 mo)** **[-35.160 - -22.240] (3-3 mo)** **[-25.381 - -13.819] (12-12 mo)**
		p-value	**0.564 (0-0 mo)** **<.0001 (3-3 mo)** **<.0001 (12-12 mo)**
		Abs. diff., %	**-1.8 (0-0 mo)** **-28.7 (3-3 mo)** **-19.6 (12-12 mo)**

Table 2. *Intergroup Comparison of Limb Functional Activity Indicators.*

Subgroup	**Group I vs Group II**			
	Study baseline	**1 month**	**3 months**	**12 months**
A N1 = 35 N2 = 32	Df=1 X2= 0.74 p-value = 0.389	Df=1 X2= 3.94 p-value = 0.045	Df=1 X2= 9.5 p-value = 0.02	Df=2 X2= 12.85 p-value = 0.002
B N1=23 N2=24	Df=1 X2= 0.009 p-value= 0.924	Df=2 X2=1.19 p-value=0.276	Df=1 X2=6.21 p-value = 0.013	Df=2 X2=9.25 p-value = 0.010

Findings:

The data clearly demonstrate that while both standard and modified management led to significant early improvement, while the modified protocol with adjuvant therapy resulted in superior preservation of gains at 12 months across both quality of life and functional activity endpoints, and in both clinical subgroups. The efficacy of therapy performed was confirmed data registered by coagulogramma data and significant improvement of blood flow parameters.

Intergroup Comparison of Limb Functional Activity Indicators in Subgroup A Patients.

The data presented in Table 6 indicate that comparative analysis of the indicators recorded immediately after surgery did not reveal statistically confirmed evidence of a correlation between pre- and postoperative management and the indicators of functional activity of the affected limb (df=1, χ^2=0.74, p=0.389). In contrast, the result of comparative analysis of ischemia severity indicators (according to the Fontaine classification) and management protocol at 1, 3, and 12 months after the start of therapy rejected the null hypothesis of proportional intergroup distribution with high probability, demonstrating evidence of pronounced correlation between certain categories (for 1, 3, and 12 months, respectively: df=1, χ^2=3.94, p=0.045; df=1, χ^2=9.5, p=0.002; df=2, χ^2=12.85, p=0.002).

Intergroup Comparison of Limb Functional Activity Indicators in Subgroup B Patients.

Comparison of these parameters one month after the start of therapy did not reveal a statistically significant association between postoperative management and functional activity indicators. At 3 and 12 months after surgery – similar to Subgroup A – the result of comparative analysis of ischemia severity indicators (according to the Fontaine classification) and the management protocol rejected the null hypothesis with high probability, demonstrating evidence of pronounced correlation between data categories (X^2=6.21, p=0.013 and X^2=9.25, p=0.010 for 3 and 12 months, respectively).

It is necessary to emphasize that in both Subgroups A and B of the second clinical group, the proportion of patients with higher levels of functional activity reliably exceeded the corresponding

indicators of the first clinical group at the 1st, 3rd, and 12th months of the study for Subgroup A, and at the 3rd and 12th months for Subgroup B.

The obtained data clearly demonstrate that the modified protocol of rehabilitative treatment for patients with arterial patency disorders provides a comparatively more pronounced and long-lasting favourable effect.

Discussion.

This comparative study demonstrates that augmenting standard post-revascularization care with a defined regimen of neurometabolic and endothelioprotective adjuvant therapy leads to significantly better-preserved lower limb function and quality of life at one-year follow-up in patients with PAD and critical limb ischemia.

The expected benefits for the combination therapy in this cohort derives from the documented efficacy of analogous drug regimens in addressing disorders across multiple somatic functions or the absence of a negative interaction effect reported [7-9].

The key finding is not just the magnitude of early improvement, which was substantial in both groups, but the durability of that improvement. The standard care group exhibited a clear trend toward regression in both Fontaine stage and SF-36 scores between 3 and 12 months. In contrast, the modified therapy group either maintained or continued to improve upon their 3-month gains. This suggests the adjuvant therapy may positively influence the underlying pathophysiology—potentially mitigating endothelial dysfunction, oxidative stress, and neural-metabolic imbalance—that contributes to disease progression and restenosis [2,4].

The benefit was consistent across patients regardless of whether the initial revascularization involved the femoral segment (Subgroup B) or not (Subgroup A), indicating the adjuvant effect is systemic and not merely local.

Our results align with the growing understanding that PAD is a systemic disorder requiring comprehensive management beyond luminal revascularization. They are consistent with studies highlighting the role of endothelial dysfunction and metabolic disturbances in PAD progression [2,4,10].

Study Limitations.

This study has limitations, including its single-center design, non-randomized allocation to treatment groups, and a modest sample size. The absence of a placebo control for the adjuvant regimen is a notable constraint. Furthermore, the specific contributions of individual components within the multi-drug adjuvant regimen cannot be discerned.

Despite these limitations, the study provides compelling preliminary hypothesis for a structured adjuvant therapeutic approach.

Conclusion.

In patients with PAD and critical limb ischemia undergoing revascularization, the addition of a 12-month regimen of neurometabolic and endothelioprotective adjuvant therapy to standard postoperative management is associated with significantly better functional capacity of lower limb (Fontaine stage) and health-related quality of life (SF-36) at one-year follow-up, compared to standard management. This combined approach appears to enhance the indicators shifts amplitudes and durability of revascularization outcomes. These findings warrant validation through large-scale, multicenter, randomized, clinical trials to definitively establish efficacy and refine the optimal adjuvant protocol.

Conflicts of Interest.

The authors declare no conflicts of interest with respect to the research, authorship, and/or publication of this article.

AI.

The authors declare that AI-based software (DeepSeek AI (by DeepSeek Company)) was used solely for initial language editing and formatting. The scientific content, interpretation, and references were entirely authored and verified by the authors.

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