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Impact of Nonhormonal Therapy for Climacteric Syndrome on the Efficacy of Antiarrhythmic Drugs in Women with Paroxysmal Atrial Fibrillation

Ruslan F. Rakhmatullov
Penza State University, Penza, Russia

ABSTRACT

BACKGROUND: The interaction between antiarrhythmic agents and nonhormonal therapies in women with paroxysmal atrial fibrillation and vasomotor symptoms associated with climacteric syndrome is clinically significant.

AIM: To investigate the relationship between the severity of vasomotor symptoms in women with climacteric syndrome and occurrence of paroxysmal atrial fibrillation and evaluate the impact of nonhormonal therapy antiarrhythmic drug efficacy.

MATERIAL AND METHODS: Eighty-seven women aged 42–59 years (mean age: 48.8 ± 1.3 years) with paroxysmal atrial fibrillation and vasomotor symptoms associated with climacteric syndrome, including hot flashes, a sensation of skipped or irregular heartbeats, tachycardia, and chest pain, were studied. The severity of vasomotor symptoms was assessed using the Greene Scale. Electrocardiography, 24-hour Holter monitoring, echocardiography, and laboratory evaluation of female sex hormone levels and the international normalized ratio were conducted. Paroxysmal atrial fibrillation therapy included amiodarone, beta-alanine, and anticoagulants. For each variable, the arithmetic mean and standard error of the mean were calculated. The distribution type was determined using the Kolmogorov–Smirnov test. Statistical significance was evaluated using the paired Student's t-test for related groups and Mann–Whitney U test for independent groups. Multivariate analysis was performed to calculate the independent predictors of atrial fibrillation recurrence. $P < 0.05$ indicated a significant difference.

RESULTS: Regression analysis showed that the number of paroxysmal atrial fibrillation episodes was associated with hot flash daily frequency (β = 1.1694, $p < 0.001$) and duration (β = –0.1239, $p = 0.0052$). Arrhythmia duration was related to hot flash frequency (β = 0.9561, $p < 0.001$), duration (β = –0.1391, $p < 0.001$), and intensity (β = 0.1735, $p = 0.0012$). Moreover, ventricular rate during paroxysmal atrial fibrillation was affected by hot flash frequency (β = 0.8893, $p < 0.001$) and intensity (β = 0.1910, $p = 0.0029$). ROC analysis revealed that a hot flash frequency > 19.5 episodes/day (AUC = 0.941), duration > 28.7 seconds (AUC = 0.918), and intensity >52.3% on the Greene Scale (AUC = 0.932) were associated with an increased paroxysmal atrial fibrillation episodes. Amiodarone combined with nonhormonal therapy reduced the frequency of paroxysmal atrial fibrillation by 78.9% ($p < 0.001$), arrhythmia duration by 54.1% ($p < 0.001$), and ventricular rate during paroxysmal atrial fibrillation by 21.6% ($p < 0.001$). The incidence rate of adverse events was 2.3%.

CONCLUSION: Vasomotor symptom severity is directly associated with paroxysmal atrial fibrillation frequency in women with climacteric syndrome. The combination of amiodarone and nonhormonal therapy demonstrates high antiarrhythmic efficacy.

Keywords: atrial fibrillation; vasomotor symptoms; climacteric syndrome; amiodarone; nonhormonal therapy.

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ОРИГИНАЛЬНОЕ ИССЛЕДОВАНИЕ
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Влияние негормональной терапии климактерического синдрома на эффективность антиаритмических средств у женщин с пароксизмальной фибрилляцией предсердий

Р.Ф. Рахматуллов
Пензенский государственный университет, г. Пенза, Россия

АННОТАЦИЯ

Актуальность. Изучение взаимодействия антиаритмических средств с негормональными препаратами у женщин с пароксизмами фибрилляции предсердий и вазомоторными симптомами при климактерическом синдроме имеет большое практическое значение.

Цель. Изучить взаимосвязь выраженности вазомоторных симптомов климактерического синдрома у женщин с пароксизмами фибрилляции предсердий и оценить влияние негормональной терапии на эффективность антиаритмических средств.

Материал и методы. В исследование были включены 87 женщин с пароксизмами фибрилляции предсердий в возрасте от 42 до 59 лет (в среднем 48,8±1,3 лет) с вазомоторными симптомами, при климактерическом синдроме, которые включали приливы, чувство перебоев в работе сердца, учащённое сердцебиение и кардиалгии. Тяжесть вазомоторных симптомов оценивали по шкале Грина. Всем женщинам проводили регистрацию электрокардиограммы, суточное мониторирование электрокардиограммы, эхокардиографию, оценку концентрации женских половых гормонов и уровня международного нормализованного отношения. Терапия фибрилляции предсердий включала лечение амиодароном, бета-аланином и антикоагулянтами. Для каждой выборки вычисляли среднее арифметическое значение (M), среднее квадратичное отклонение (m). Вид распределения оценивали с помощью теста Колмогорова–Смирнова. При расчёте статистической значимости в двух связанных группах использовали t-критерий Стьюдента, а в двух несвязанных группах — критерий Манна–Уитни. Для расчёта независимых предикторов рецидивирования фибрилляции предсердий применяли многофакторный анализ. Различия считали достоверными при p <0,05.

Результаты. Регрессионный анализ показал, что на количество пароксизмов фибрилляции предсердий влияет частота приливов в сутки (β=1,1694, p <0,001) и продолжительность (β=–0,1239, p=0,0052) приливов в секундах, на продолжительность аритмии — частота (β=0,9561, p <0,001), продолжительность (β=–0,1391, p <0,001) и интенсивность (β=0,1735, p=0,0012) приливов, на частоту желудочковых сокращений — частота (β=0,8893, p <0,001) и интенсивность (β=0,1910, p=0,0029) приливов. ROC-анализ выявил, что при увеличении частоты приливов более чем 19,5 раза в сутки (AUC=0,941), продолжительности приливов более чем 28,7 с (AUC=0,918) и увеличении процента интенсивности тяжёлых приливов по шкале Грина больше чем 52,3% (AUC=0,932) возникает увеличение количества пароксизмов фибрилляции предсердий. Установлено, что антиаритмическая эффективность комбинации амиодарона с негормональной терапией уменьшила количество пароксизмальной фибрилляции предсердий на 78,9% (p <0,001), продолжительность аритмии на 54,1% (p <0,001) и частоту желудочковых сокращений во время пароксизмальной фибрилляции предсердий на 21,6% (p <0,001). Число побочных проявлений составило 2,3%.

Заключение. Установлена прямая связь выраженности вазомоторных симптомов при климактерическом синдроме у женщин с пароксизмами фибрилляции предсердий. Выявлена высокая антиаритмическая эффективность комбинации амиодарона с негормональной терапией.

Ключевые слова: фибрилляция предсердий; вазомоторные симптомы; климактерический синдром; амиодарон; негормональная терапия.

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BACKGROUND

Improving the effectiveness of atrial fibrillation (AF) treatment in women with vasomotor symptoms associated with climacteric syndrome remains crucial in contemporary cardiology [1–3]. Several studies have demonstrated the high antiarrhythmic efficacy and prolonged duration of action of amiodarone [4–6].

Multicenter studies have shown that the use of menopausal hormone therapy increases the risk of AF; therefore, in this patient population, nonhormonal drugs are recommended to relieve vasomotor disorders in climacteric syndrome [7–9].

Despite the accumulated experience of using amiodarone in clinical practice, its role in the treatment of paroxysmal AF (PAF) in women with vasomotor symptoms of climacteric syndrome receiving nonhormonal therapy (NHT) is unclear, and its impact on the course of arrhythmia remains insufficiently studied.

This study aimed to investigate the relationship between severity of vasomotor symptoms of climacteric syndrome in women and paroxysmal AF and assess the effect of NHT on the efficacy of antiarrhythmic drugs.

MATERIAL AND METHODS

The study included 87 women with PAF, with mild to moderate symptoms (IIa and IIb according to the mEHRA classification), aged 42–59 years (mean age: 48.8 ± 1.3 years) who presented with vasomotor symptoms of moderate (35–58 points on the Greene Climacteric Scale) or severe (>59 points on the Greene scale) intensity associated with climacteric syndrome.

The most common vasomotor symptoms in women with climacteric syndrome were hot flashes, heart rhythm disturbances, palpitations, and cardialgia. The chest pain was nonanginal in nature and was classified as acute (28.7%) or prolonged (71.3%). Acute pain was described as stabbing, aching, cutting, or burning. Prolonged chest pain was dull, not intense, persisting for several months or even years and was accompanied by heaviness in the heart region.

The study excluded women with hypertension, coronary artery disease, cardiomyopathy, active inflammatory myocardial processes, valvular disease, New York Heart Association functional class II–IV heart failure, or thyroid disorders.

All women underwent electrocardiography (ECG), 24-hour ambulatory ECG monitoring (Holter monitoring), echocardiography, and assessment of sex hormone levels and international normalized ratio and completed the Greene Climacteric Scale questionnaire.

Holter ECG monitoring was performed to assess the number and duration of paroxysmal AF episodes, including ventricular rate (VR) during arrhythmia, using the Astrokard system (ZAO Medtek).

Echocardiography was conducted during sinus rhythm using the Ruscan-65 system (NPO Spektr, Russia). The following parameters were assessed: aortic wall condition at the level of the valves and ascending aorta, left ventricular end-diastolic and end-systolic volumes and their indices, ejection fraction, stroke volume and cardiac index, anteroposterior diameter and volume of the left atrium (LA), and atrioventricular ratio (i.e., LA diameter divided by the left ventricular end-diastolic diameter). All echocardiographic parameters were within normal ranges, as patients with hypertension, coronary artery disease, cardiomyopathy, active inflammatory myocardial disease, valvular heart disease, or clinically significant heart failure were excluded. Aortic wall thickening indicating atherosclerosis was observed in 35 patients (40.2%). The mean end-diastolic volume was 92.6 ± 3.5 mL; end-diastolic volume index, 60.1 ± 1.6 mL/m^2; end-systolic volume, 39.4 ± 2.1 mL; end-systolic volume index, 22.3 ± 1.4 mL/m^2; LA diameter, 28.9 ± 0.7 mm; LA index, 17.4 ± 0.8 mm/m^2; atrioventricular ratio, 0.56 ± 0.02; and ejection fraction, 66.5 ± 1.8%. The baseline echocardiographic parameters were normal; thus, changes in these values during therapy with amiodarone and beta-alanine were not assessed.

Serum levels of estradiol, luteinizing hormone, follicle-stimulating hormone, the luteinizing hormone and follicle-stimulating hormone ratio, estrone, total testosterone, bound testosterone, sex hormone-binding globulin, and inhibin B were measured using an electrochemiluminescence immunoassay (Cobas 8000; Roche Diagnostics, Switzerland).

The patients completed the Greene Climacteric Scale questionnaire to assess the severity of climacteric syndrome [10]. Notably, 23 women scored 35–58 points, and 64 scored >59 points.

All patients had received antiarrhythmic therapy before study enrollment. Treatment regimens included either monotherapy or combination therapy. Monotherapy was administered with metoprolol, sotalol, lappaconitine hydrobromide (Allapinin®), propafenone, or amiodarone, whereas combination therapy included metoprolol (or sotalol or amiodarone) combined with lappaconitine hydrobromide or propafenone.

Antiarrhythmic therapy was considered effective if the number of paroxysmal AF episodes reduced by ⩾70%.

Ongoing therapy resulted in a reduction in the number of paroxysmal AF episodes by 20%–25% in 22 women (25.3%) and by 50% in 18 women (20.7%). However, antiarrhythmic therapy was ineffective in 47 patients (54%), and radiofrequency ablation of the pulmonary veins was ineffective in 3 women (3.4%). Data analysis showed that the lack of effectiveness of antiarrhythmic therapy was associated with persistent clinical manifestations of vasomotor symptoms. During amiodarone therapy, four trends were observed: reduction in heart rate during paroxysmal AF episodes at rest and during physical exertion, improved arrhythmia tolerance, and increased exercise capacity. All 4 positive effects were noted in 15 women (17.2%), 3 in 20 women (23.0%), 2 in 30 women (34.5%), 1 in 16 women (18.4%), and none in 6 women (6.9%). Considering the favorable properties of amiodarone, the drug was used in combination with NHT.

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Table 1. Impact of the administered therapy on sex hormone levels, vasomotor symptoms, and atrial fibrillation episodes in women with climacteric syndrome

Parameters	Outcome (n = 87) 1	Beta-alanine (n = 87) 2	Amiodarone + Beta-alanine (n = 87) 3
Estradiol, pg/mL	43.7 ± 4.1	43.6 ± 3.4 $p_{1-2} = 0.235$	45.3 ± 3.8 $p_{1-3} = 0.746$
LH, mIU/L	59.4 ± 4.3	70.2 ± 5.6 $p_{1-2} = 0.445$	68.5 ± 4.9 $p_{1-3} = 0.52$
FSH, mIU/L	94.6 ± 7.3	99.7 ± 6.8 $p_{1-2} = 0.914$	94.6 ± 7.5 $p_{1-3} = 0.283$
LH/FSH	0.59 ± 0.011	0.57 ± 0.009 $p_{1-2} = 0.097$	0.61 ± 0.008 $p_{1-3} = 0.828$
Estrone, pg/mL	12.1 ± 0.98	13.5 ± 1.1 $p_{1-2} = 0.746$	12.5 ± 0.94 $p_{1-3} = 0.515$
Total testosterone, nmol/L	0.55 ± 0.053	0.62 ± 0.048 $p_{1-2} = 0.995$	0.51 ± 0.062 $p_{1-3} = 0.914$
Bound testosterone, nmol/L	0.012 ± 0.0092	0.014 ± 0.0073 $p_{1-2} = 0.589$	0.016 ± 0.0081 $p_{1-3} = 0.83$
SHBG, nmol/L	16.3 ± 1.4	18.1 ± 1.5 $p_{1-2} = 0.828$	15.8 ± 2.1 $p_{1-3} = 0.314$
Inhibin B, pg/mL	9.8 ± 0.67	9.3 ± 0.72 $p_{1-2} = 0.74$	9.6 ± 0.58 $p_{1-3} = 0.224$
Hot flash frequency, per day	18.5 ± 1.5	10.5 ± 0.76 $p_{1-2} < 0.001$	5.5 ± 0.31 $p_{1-3} < 0.001$
Hot flash duration, s	25.6 ± 1.8	14.2 ± 0.82 $p_{1-2} < 0.001$	6.9 ± 0.26 $p_{1-3} < 0.001$
Hot flash intensity	+++	++	+
Percentage of severe hot flashes	50.5 ± 3.8	20.6 ± 1.3 $p_{1-2} < 0.001$	9.8 ± 0.5 $p_{13.5} < 0.001$
Number of PAF episodes per year	23.6 ± 2.0	13.1 ± 0.98 $p_{1-2} < 0.001$	6.0 ± 0.41 $p_{1-3} < 0.001$
Duration of PAF episodes, min	26.1 ± 1.8	14.7 ± 1.5 $p_{1-2} < 0.001$	7.2 ± 0.13 $p_{1-3} < 0.001$
Ventricular rate during PAF, bpm	114.4 ± 4.3	100.5 ± 3.1 $p_{1-3} < 0.001$	82.3 ± 1.5 $p_{1-5} < 0.001$

Note: NHT, nonhormonal therapy; LH, luteinizing hormone; FSH, follicle-stimulating hormone; SHBG, sex hormone-binding globulin; PAF, paroxysmal atrial fibrillation; bpm, beats per minute.

Table 2. Results of the multiple regression analysis of atrial fibrillation in relation to hot flash frequency, duration, and intensity in women

Parameter	ß	t	p	ß	t	p	ß	t	p
Dependent variable	—	Number	AF	Duration		AF	VR	during	AF
Multiple correlation coefficient (R)	—	0.996	—	—	0.985	—	—	0.992	—
Coefficient of determination (R^2)	—	0.991	—	—	0.976	—	—	0.989	—
Fisher's test statistic (F)	—	1171.3	$p < 0.001$	—	1443.6	$p < 0.001$	—	976.6	$p < 0.001$
Hot flash frequency, per day	1.1694	19.0	$p < 0.001$	0.9561	17.2	$p < 0.001$	0.8893	13.2	$p < 0.001$
Hot flash duration, s	–0.1239	–3.1	$p = 0.0052$	–0.1391	–3.8	$p < 0.001$	–0.0851	–1.9	$p = 0.0682$
Percentage of severe hot flashes	–0.0656	–1.22	$p = 0.2301$	0.1735	3.6	$p = 0.0012$	0.1910	3.4	$p = 0.0029$

NHT for vasomotor symptoms in climacteric syndrome was prescribed by a gynecologist. Beta-alanine was used to control symptoms, with the dosage determined based on symptom severity according to the Greene Climacteric Scale. For women with moderate symptoms ($n = 23$), the dose was 400 mg twice daily. For those with severe symptoms ($n = 64$), the dose was 400 mg three times daily.

Anticoagulant therapy was prescribed to 35 women (40.2%) with a CHA_2DS_2-VASc score ⩾ 1.

Statistical analysis was performed using the Statistica 13.3 software. The arithmetic mean and standard deviation for each sample were calculated. The distribution type was assessed using the Kolmogorov–Smirnov test. The paired Student's t-test was utilized to determine statistical significance between the two related groups, and the Mann–Whitney U test was applied for the two independent groups. Multivariate analysis was employed to identify the independent predictors of AF recurrence. Receiver operating characteristic (ROC) analysis was used to evaluate the impact of individual parameters. This method assesses the quality of the binary classification and shows the relationship between the proportion of true positives among all the actual positives and proportion of false positives among all the actual negatives. Threshold values for quantitative predictors were determined based on ROC analysis at the optimal sensitivity-to-specificity ratio. Differences were considered significant at $p < 0.05$.

RESULTS

Table 1 presents the outcomes of paroxysmal atrial fibrillation treatment in women with vasomotor symptoms of climacteric syndrome using combined amiodarone and nonhormonal therapy.

Data analysis showed that NHT alone or in combination with amiodarone had no significant effect ($p > 0.05$) on female sex hormone levels (Table 1). These findings are consistent with those in previous studies demonstrating that antiarrhythmic therapy and NHT do not alter female sex hormone metabolism [11, 12].

NHT led to a 44.6% reduction in hot flash frequency ($p < 0.001$), 48.3% reduction in their duration ($p < 0.001$), and 58.8% reduction in the percentage of severe hot flashes ($p < 0.001$) (Table 1). The conducted NHT, as a result of the reduction in the number and duration of hot flashes and percentage of severe hot flashes, led to a decrease in the frequency of PAF episodes by 44.5% ($p < 0.001$).

The most pronounced antiarrhythmic effect was noted in combined amiodarone and NHT. The duration of PAF episodes decreased by 78.9% ($p < 0.001$), the duration of arrhythmia by 54.1% ($p < 0.001$), and the VR during PAF by 21.6% ($p < 0.001$).

Several studies have reported that adverse effects occur in 6%–9% of patients receiving amiodarone therapy [13, 14]. The present study reveals a lower incidence of adverse effects when amiodarone is used in combination with NHT. In this study, only 2 women (2.3%) experienced adverse effects in the form of photosensitization during 2 and 4 years of amiodarone therapy.

Table 3. Results of ROC analysis of atrial fibrillation in relation to hot flash frequency, duration, and severity

Parameters	TV	TPR	FPR	AUC	SE
Hot flash frequency, per day	>19.5	100.0	72.7	0.941	0.058
Hot flash duration, s	>28.7	100.0	63.6	0.918	0.064
Percentage of severe hot flashes	>52.3	85.0	91.0	0.932	0.052

Note: TV, threshold value; TPR, true positive rate (sensitivity); FPR, false positive rate (specificity); AUC, area under the curve; SE, standard error.

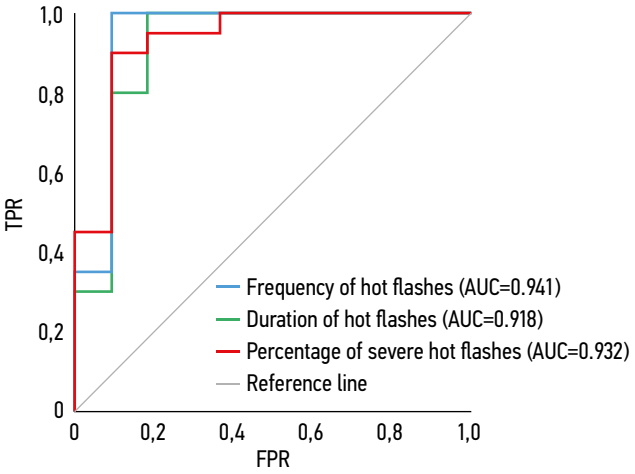

Fig. 1. ROC curves illustrating threshold levels for hot flash frequency, duration, and proportion of severe hot flashes in women with atrial fibrillation. TPR, sensitivity; FPR, specificity; AUC, area under the curve.

Table 2 presents the results of multiple regression analysis examining the associations of PAF frequency, PAF duration, and VR during PAF with the frequency, duration, and percentage of severe hot flashes.

Based on obtained data, an association between paroxysmal AF parameters and vasomotor symptoms in climacteric syndrome was identified (Table 2). Moreover, it was found that the duration of PAF episodes and VR during PAF were influenced by the frequency, duration, and percentage of severe hot flashes.

These indicate that NHT in women affects the clinical course of PAF. Correction of vasomotor symptoms during antiarrhythmic therapy enhances short- and long-term therapeutic efficacy and reduces the incidence of adverse effects.

The next stage of the study was to assess the threshold value of frequency, duration, and severity of hot flashes for increasing the number of paroxysmal AF episodes. ROC analysis was performed to evaluate the threshold value for the frequency, duration, and severity of hot flashes in PAF. The results are presented in Table 3 and Fig. 1.

Table 3 indicates a direct relationship between the hot flash parameters and frequency of AF episodes in women with climacteric syndrome.

Several authors have revealed that an imbalance in reproductive hormones and the severity of vasomotor symptoms in climacteric syndrome are crucial in the initiation and maintenance of PAF [15, 16]. ROC analysis confirmed an association between vasomotor symptoms and PAF. Moreover, the pathophysiological mechanisms linking female sex hormone levels, vasomotor symptoms, and PAF remain poorly understood.

Thus, regression and ROC analyses demonstrated a relationship between vasomotor symptoms in climacteric syndrome and PAF, supporting the rationale for the combined use of amiodarone and nonhormonal therapy.

CONCLUSION

PAF is directly associated with the frequency, duration, and intensity of hot flashes in women with climacteric syndrome.

In women with PAF and vasomotor symptoms associated with climacteric syndrome, combined amiodarone and beta-alanine therapy demonstrated high antiarrhythmic efficacy and low incidence of adverse effects.

ADDITIONAL INFORMATION

Author contributions: R.F.R.: investigation, data curation, writing—original draft, and writing—review & editing. The author approved the version of the manuscript to be published and agrees to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
Ethics approval: The study was approved by the Local Ethics Committee of Penza State University (Protocol No. 6, dated March 30, 2018; and Protocol No. 10, dated June 28, 2024). All participants provided written informed consent prior to inclusion in the study.
Informed consent: The author obtained written informed consent from the patients for the publication of personal data, including photographs with concealed facial features, in a scientific journal and its online version (signed on September 4, 2020). The scope of the published data was approved by the patients.
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ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Вклад автора: Р.Р.Ф. — проведение исследования, работа с данными, написание черновика, пересмотр и редактирование рукописи. Автор одобрил рукопись (версию для публикации), а также согласился нести ответственность за все аспекты работы, гарантируя надлежащее рассмотрение и решение вопросов, связанных с точностью и добросовестностью любой её части.
Этическая экспертиза. Проведение исследования одобрено локальным этическим комитетом при Пензенском государственном университете (протокол № 6 от 30.03.2018 и протокол № 10 от 28.06.2024). Все участники исследования добровольно подписали форму информированного согласия до включения в исследование.
Согласие на публикацию. Автор получил письменное информированное добровольное согласие пациентов на публикацию персональных данных, в том числе фотографий (с закрытием лица), в научном журнале, включая его электронную версию (дата подписания: 04.09.2020). Объём публикуемых данных с пациентами согласован.
Источники финансирования. Отсутствуют.
Раскрытие интересов. Автор заявляет об отсутствии отношений, деятельности и интересов за последние три года, связанных с третьими лицами (коммерческими и некоммерческими), интересы которых могут быть затронуты содержанием статьи.
Оригинальность. При создании настоящей работы автор не использовал ранее опубликованные сведения (текст, иллюстрации, данные).
Доступ к данным. Все данные, полученные в настоящем исследовании, доступны в статье.
Генеративный искусственный интеллект. При создании настоящей статьи технологии генеративного искусственного интеллекта не использовали.
Рассмотрение и рецензирование. Настоящая работа подана в журнал в инициативном порядке и рассмотрена по обычной процедуре. В рецензировании участвовали три внешних рецензента, член редакционной коллегии и научный редактор издания.

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AUTHOR INFO

Ruslan F. Rakhmatullov, MD, Cand. Sci. (Medicine),
Assistant Professor, Depart. of Internal Diseases;
address: 40 Krasnaya st, Penza, Russia, 440026;
ORCID: 0000-0002-2157-544X;
eLibrary SPIN: 5748-7530;
e-mail: capitalofgreat@icloud.com

ОБ АВТОРЕ

Рахматуллов Руслан Фагимович, канд. мед. наук, доцент,
каф. внутренних болезней;
адрес: Россия, 440026, Пенза, ул. Красная, д. 40;
ORCID: 0000-0002-2157-544X;
eLibrary SPIN: 5748-7530;
e-mail: capitalofgreat@icloud.com