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# Application of the complex Edelim in pathogenetic management of patients with erectile dysfunction

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**AIM:** To assess the degree of changes in complaints, dynamics of biochemical parameters of lipid metabolism, penile hemodynamics in patients with ED during therapy with EDELIM in comparison with PDE-5 inhibitors. Assess the tolerability of the drug based on the analysis of reported adverse events.

**MATERIALS AND METHODS:** The study was prospective comparative observational cohort. The study included 60 patients over 18 years old with complaints of persistent, at least 1 month, erectile dysfunction. The patients were divided into 2 groups: group 1 – patients with ED received Edelim on a regular basis, one capsule 2 times daily for 3 months; group 2 – patients with ED received generic tadalafil 5 mg daily for 1 month, then 1 month break, then 5 mg per day for 1 month.

**RESULTS:** The mean age of the patients was  $38.4 \pm 9.2$  years. In group 1, significant differences were noted in the all hemodynamic and biochemical indicators, except for HDL levels ( $2.2 \pm 0.4$  vs.  $2.3 \pm 0.4$  mmol/L;  $p = 0.067$ ). In group 2, significant differences were noted in the dynamics of the IIEF-5 scale, the level of HDL, and the blood flow velocity in the right and left cavernous arteries. There were no significant differences in blood flow in the left and right dorsal arteries, levels of total cholesterol, LDL, triglycerides, glucose, HbA1c, systolic blood pressure. In the 1st group of patients, there were no adverse events, in the 2nd group, in 3 patients – mild side effects.

**CONCLUSIONS:** The improvement in the quality of erection in the group of patients taking Edelim is associated with decrease in the lipid profile, glucose, glycated hemoglobin, which can be regarded as a variant of pathogenetic conservative treatment of ED.

**Keywords:** erectile dysfunction; Edelim; conservative treatment; penile hemodynamics.

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# Применение комплекса «Эделим» в патогенетическом лечении пациентов с эректильной дисфункцией

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**Цель исследования.** Оценить степень изменения жалоб, динамику биохимических параметров липидного обмена, пенильную гемодинамику у пациентов с эректильной дисфункцией на фоне терапии комплексом «Эделим» в сравнении с ингибиторами фосфодиэстеразы 5-го типа. Оценить переносимость препарата на основе анализа зарегистрированных нежелательных явлений.

**Материалы и методы.** Исследование проводилось как проспективное сравнительное наблюдательное когортное. В исследование включены 60 пациентов старше 18 лет с жалобами на стойкое, не менее 1 мес., снижение качества эреций. Пациенты с эректильной дисфункцией были разделены на 2 группы: в группе 1 — получали комплекс «Эделим» на регулярной основе по одной капсуле (410 мг) 2 раза в день в течение 3 мес.; в группе 2 — получали воспроизведенный препарат тадалафила по 5 мг в сутки в течение 1 мес., затем 1 мес. перерыва, затем вновь по 5 мг в сутки в течение 1 мес.

**Результаты.** Средний возраст пациентов составил  $38,4 \pm 9,2$  года. В группе 1 при сравнении показателей до и после лечения отмечались достоверные различия в динамике всех гемодинамических и биохимических показателей, кроме уровня ЛПВП ( $2,2 \pm 0,4$  vs.  $2,3 \pm 0,4$  ммоль/л;  $p = 0,067$ ). В группе 2 достоверные различия отмечались в динамике оценки по шкале МИЭФ-5, уровня ЛПВП и скорости кровотока по правой и левой кавернозных артерий. Не были отмечены достоверные различия в кровотоках по левой и правой дорсальным артериям, уровнях общего холестерина, ЛПНП, триглицеридов, глюкозы, HbA1c, систолическом артериальном давлении. В группе 1 у пациентов нежелательных явлений выявлено не было, в группе 2 у трех пациентов выявлены легкие побочные действия.

**Заключение.** Таким образом, улучшение качества эрекции в группе пациентов, принимавших комплекс «Эделим», связано со снижением показателей липидного профиля, глюкозы, гликированного гемоглобина, что можно расценивать как патогенетический подход к ведению пациентов с эректильной дисфункцией.

**Ключевые слова:** эректильная дисфункция; Эделим; консервативная терапия; пенильная гемодинамика.

## Как цитировать:

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## INTRODUCTION

Erectile dysfunction (ED) is the inability to achieve and/or maintain an erection sufficient for intercourse, which can occur periodically and permanently [1]. ED impairs significantly a man's quality of life [2]. ED is not only a medical problem, but also has social significance [3].

Epidemiological studies have shown a high prevalence and incidence of ED, which ranges from 16% to 25% in different countries. According to the Massachusetts Male Aging Study in Boston, 52% of 40–70-year-old men have ED. The incidence of ED increases with age. A study performed in six European countries, namely, France, Germany, Italy, Netherlands, Spain, and United Kingdom, and the USA revealed that the overall prevalence of ED was 49%, and 10% of patients reported complete absence of erection [4]. Regarding the epidemiological component of ED, in Russia, of the 1225 patients aged 20–75 years, 1101 exhibited signs of ED. In 10.1% of the cases, no signs of ED were detected; mild ED was found in 71.3%, moderate ED was detected in 6.6%, and severe disorders were noted in 12%. Of the 1225 men, 115 discontinued sexual activity, while ED became the etiological factor in 69.6% [5].

ED is a multifactorial syndrome [6]. Erectile function is affected by existing cardiovascular diseases, arterial hypertension, diabetes mellitus, hormonal disorders, as well as a history of radiation therapy in the pelvic or retroperitoneal space, trauma, and spinal cord disorders [7, 8]. The most common mechanism of ED is endothelial dysfunction, which is associated with insufficient production of nitric oxide (NO) by the vascular endothelium in response to stimuli [9].

Pathogenetic treatment of ED is still a relevant issue in urology [10–12]. In most cases, urologists have applied symptomatic treatment methods to treat ED. These include the intake of phosphodiesterase type 5 (PDE5) inhibitors, falloendoprosthetics, and intracavernous injections of drugs [13–15]. Pathogenetic methods of treatment include revascularization of the penis, reduction of the venous outflow (ligation of deep or endovascular occlusion of the deep dorsal vein), and shockwave therapy [16–19].

Until now, the issue of drug pathogenetic treatment for ED remains unresolved. Considering the etiology and pathogenesis of ED, in some cases, the intake of drugs and change in lifestyle, which lead to the normalization of indicators that affect erectile function, a positive effect can be obtained not only on other organs and systems but also on potency. However, these drugs have an off-label prescription for the treatment of ED [20, 21].

Edelim is the first drug registered in the Russian Federation that affects ED development. Edelim is registered as a biologically active food supplement. A standard

410 mg capsule contains 250 mg of garlic extract, 100 mg of psyllium husk extract, 50 mg of red sage root extract, and 720 µg of chromium picolinate. Auxiliary components are gelatin (in the capsule shell), titanium dioxide (dye in the capsule shell), iron oxide (dye in the capsule shell), and AEROSIL (anti-caking agent).

*This study aimed* to assess the efficiency (increase in the frequency of episodes and quality of erections) and the degree of changes in the complaints of patients with ED during treatment with Edelim, to assess the dynamics of biochemical parameters of lipid metabolism in patients with ED while taking Edelim, and to assess tolerance to Edelim based on the analysis of adverse events.

## MATERIALS AND METHODS

A prospective comparative observational cohort study was conducted in the urology and andrology center of the A.I. Burnazyan State Scientific Center, Federal Medical Biophysical Center, Federal Medical and Biological Agency of Russia, and the urology department of the M.A. Podgorbunsky Kuzbass Clinical Emergency Hospital.

The study included 60 patients aged >18 years with complaints of persistent, for at least 1 month, decrease in the quality of erections. The exclusion criteria, in addition to the standard ones (such as inability to provide adequate answers to researcher's questions, chronic alcoholism, and severe concomitant diseases), were the intake of testosterone drugs or gonadotropins and presence of Peyronie's disease. All study participants signed an informed consent form.

The exclusion criteria were as follows: patients who used testosterone (its esters or gonadotropins), PDE5 inhibitors (except for separately specified cases), and preparations of yohimbine; patients who underwent intracavernous injection therapy; and patients who received other drugs to improve erectile function, statins, and/or other lipid-lowering therapy during the study period.

Patients with ED participating in the study were distributed into two groups:

- Group 1 received Edelim regularly, including one capsule (410 mg) two times a day for 3 months.
- Group 2 received a generic drug tadalafil 5 mg per day for 1 month, followed by 1 month of cessation, and then 5 mg per day for 1 month.

Treatment efficiency was assessed after its completion based on the results of a survey of patients using the International Index of Erectile Function (IIEF-5) questionnaire and findings of the Doppler study of the penile vessels. Before and after the study, all patients underwent a biochemical blood test to measure levels of total cholesterol, low-density lipoproteins (LDL), high-density lipoproteins (HDL), triglycerides, glucose, and glycated hemoglobin.

Statistical analysis was performed using SPSS v. 23 (IBM Corp., Armonk, NY, USA). To confirm the significance of the differences in the baseline values of the study variables, the *t*-test was used for unrelated samples if the variables had a normal distribution and Wilcoxon signed-rank test was used for related samples if the variables had an abnormal distribution. All characteristics were tested for normality using the Kolmogorov–Smirnov test with Lilliefors correction of

significance. The threshold value for the difference of the variable distribution from the normal was set as  $p > 0.05$ .

## RESULTS

On average, the patients were  $38.4 \pm 9.2$  years old. Comparative characteristics of groups 1 and 2 are presented in Table 1.

**Table 1.** Comparative characteristics of patients in groups 1 and 2 ( $n = 60$ )

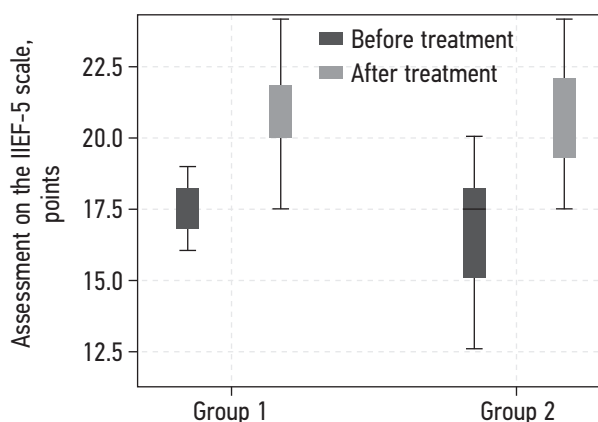
**Таблица 1.** Сравнительная характеристика пациентов 1-й и 2-й групп ( $n = 60$ )

Indicator	Group	<i>N</i>	Mean	Standard deviation	Significance for the Kolmogorov–Smirnov test	Significance of the <i>t</i> -test for equality of means
Age, years	1	30	38.2	8.1	<0.001	0.804
	2	30	38.7	10.4		
IIEF-5, points	1	30	17.2	1.7	<0.001	0.17
	2	30	16.5	2.1		
Right dorsal artery, cm/s	1	30	16.5	2.6	0.083*	0.877
	2	30	16.6	2.3		
Left dorsal artery, cm/s	1	30	17.0	2.8	0.2*	0.139
	2	30	18.3	3.7		
Right cavernous artery, cm/s	1	30	18.1	2.9	0.01	0.195
	2	30	17.0	3.3		
Left cavernous artery, cm/s	1	30	19.8	3.7	0.049	0.177
	2	30	18.3	4.7		
Total cholesterol, mmol/l	1	28	5.4	0.3	0.017	0.057
	2	30	5.1	0.7		
LDL, mmol/l	1	28	3.7	1.0	<0.001	0.002
	2	30	4.4	0.4		
HDL, mmol/l	1	28	2.2	0.4	<0.001	<0.001
	2	30	1.8	0.3		
Triglycerides, mmol/l	1	28	2.0	0.4	<0.001	0.004
	2	30	1.7	0.3		
Glucose, mmol/l	1	28	5.4	0.9	<0.001	0.498
	2	30	5.6	0.5		
HbA1c, %	1	28	5.3	0.5	0.024	0.862
	2	30	5.4	0.4		
Systolic BP, mm Hg	1	30	121.5	1.3	<0.001	0.001
	2	30	125.0	3.7		
Diastolic BP, mm Hg	1	30	78.5	3.5	<0.001	0.146
		30	77.3	2.5		

\* The distribution of this parameter differs from the normal. *Note.* *N*, number of valid values; LDL, low-density lipoprotein; HDL, high-density lipoprotein; HbA1c, glycated hemoglobin; BP, blood pressure.

In group 1, significant differences were found in the dynamics of all hemodynamic and biochemical parameters before and after treatment, except for HDL ( $2.2 \pm 0.4$  vs.  $2.3 \pm 0.4$  mmol/L;  $p = 0.067$ ). In group 2, significant differences were noted in the results of the survey using the IIEF-5 questionnaire (Fig. 1), HDL level, and blood flow velocity in the right and left cavernous arteries. No significant differences were found in the blood flow in the left and right dorsal arteries, total cholesterol, LDL, triglycerides, glucose, HbA1c, and systolic blood pressure.

In groups 1 and 2, no significant dynamics were found in total IIEF-5 scores (Table 2). No adverse events were recorded in group 1. However, in group 2, three patients had nasal congestion, hot flushes, and moderate headaches, which are classic side effects characteristic of PDE5 inhibitors.



**Fig. 1.** Dynamics of the assessment of erectile function in patients of the 1st and 2nd groups according to the IIEF-5 scale

**Рис. 1.** Динамика оценки эректильной функции больных 1-й и 2-й групп по шкале МИЭФ-5

**Table 2.** The results of statistical analysis in groups 1 and 2

**Таблица 2.** Результаты статистического анализа 1-й и 2-й групп

Parameters	Group	Before treatment	After treatment	Significance, $p$
IIEF 5, points	1	$17.2 \pm 1.7$	$20.7 \pm 1.9$	<0.001
	2	$16.5 \pm 2.0$	$21.1 \pm 2.0$	<0.001
Right dorsal artery, cm/s	1	$16.5 \pm 2.7$	$19.4 \pm 2.6$	0.04
	2	$16.6 \pm 2.3$	$18.9 \pm 2.9$	0.099
Left dorsal artery, cm/s	1	$17.0 \pm 2.9$	$19.5 \pm 3.3$	<0.001
	2	$18.3 \pm 3.8$	$18.9 \pm 3.0$	0.294
Right cavernous artery, cm/s	1	$18.1 \pm 3.0$	$19.8 \pm 1.9$	<0.001
	2	$17.0 \pm 3.3$	$19.0 \pm 2.8$	0.001
Left cavernous artery, cm/s	1	$19.8 \pm 3.7$	$21.2 \pm 2.9$	<0.001
	2	$18.3 \pm 3.8$	$20.0 \pm 4.3$	0.001
Total cholesterol, mmol/l	1	$5.4 \pm 0.4$	$4.9 \pm 0.4$	<0.001
	2	$5.1 \pm 0.7$	$5.1 \pm 0.7$	0.173
LDL, mmol/l	1	$3.7 \pm 1.0$	$3.3 \pm 1.0$	<0.001
	2	$4.4 \pm 0.5$	$4.5 \pm 0.5$	0.05
HDL, mmol/l	1	$2.2 \pm 0.4$	$2.3 \pm 0.4$	0.067
	2	$1.8 \pm 0.3$	$1.9 \pm 0.4$	0.002
Triglycerides, mmol/l	1	$2.0 \pm 0.4$	$1.8 \pm 0.3$	0.002
	2	$1.7 \pm 0.3$	$1.7 \pm 0.3$	0.074
Glucose, mmol/l	1	$5.4 \pm 1.0$	$5.1 \pm 0.8$	0.001
	2	$5.6 \pm 0.6$	$5.6 \pm 0.3$	0.760
HbA1c, %	1	$5.3 \pm 0.6$	$5.2 \pm 0.5$	0.01
	2	$5.4 \pm 0.4$	$5.4 \pm 0.3$	0.703
Systolic BP, mm Hg	1	$121.5 \pm 4.4$	$114.8 \pm 5.3$	<0.001
	2	$125.0 \pm 3.7$	$123.3 \pm 4.0$	0.599
Diastolic BP, mm Hg	1	$78.5 \pm 3.5$	$79.0 \pm 4.6$	0.03
	2	$77.3 \pm 2.5$	$72.7 \pm 4.5$	<0.001

Note. LDL, low-density lipoprotein; HDL, high-density lipoprotein; HbA1c, glycated hemoglobin; BP, blood pressure.

## CONCLUSION

The results of this study revealed a significant improvement on the IIEF-5 score and an increase in the blood flow velocity along the penile arteries in both groups. Edelim has a positive effect comparable to tadalafil on biochemical and hemodynamic parameters in patients with ED. Thus, the improvement in the quality of erection in patients taking Edelim is associated with a decrease in the indices of lipid profile and levels of

glucose and glycated hemoglobin, which can be regarded as an alternative of the pathogenetic approach to the management of patients with ED.

## ADDITIONAL INFORMATION

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**Conflict of interest.** The authors declare no conflict of interest.

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