

## EFFICACY OF TADALAFIL-SZ IN THE TREATMENT OF ERECTILE DYSFUNCTION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND WITH PREDIABETES

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⊗ The aim of the study was to evaluate the effectiveness of Tadalafil-SZ in treatment of erectile dysfunction in men suffering from type 2 diabetes mellitus or prediabetes. Two patient groups of thirty people with type 2 diabetes mellitus and prediabetes were identified. Patients' mean age was  $52.2 \pm 3.4$  years and  $48.5 \pm 2.8$  years in groups with type 2 diabetes mellitus and prediabetes respectively. All patients suffered from erectile dysfunction, which significantly reduced their quality of life. To assess the erectile function, the ICEF (International Index of Erectile Function) and QoL (Quality of Life) questionnaires were used. Patients with prediabetes took Tadalafil-SZ 5 mg once a day for 3 months and patients with type 2 diabetes mellitus took Tadalafil-SZ 20 mg 2 times a week (Monday and Thursday) for 3 months as a treatment for erectile dysfunction. Results of this study showed that the administration of Tadalafil-SZ not only led to a significant improvement in the quality of life, a significant reduction in weight, body mass index, waist size in patients of both groups, but also led to a glycated hemoglobin level normalization without increasing the dose of glucose-lowering therapy in patients with uncomplicated type 2 diabetes mellitus and a pronounced decrease in morning insulin levels measured in the blood in patients with prediabetes. Almost half of patients in both groups increased testosterone blood level. According to the ICEF questionnaire, erectile function was significantly improved: in the group of patients with prediabetes: the ICEF-5 index prior to taking Tadalafil-SZ averaged 18.68 points (mild ED) whereas after taking the drug, a statistically significant increase in the ICEF index to an average of 23.02 points ( $p < 0.05$ ) was observed, which indicates the absence of erectile dysfunction in this group of patients during intake of Tadalafil-SZ. In the 2<sup>nd</sup> group of patients (with type 2 diabetes mellitus), the ICEF-5 index before treatment averaged 12.18 points, which reflects the average degree of erectile dysfunction, and at the end of the study there was a statistically significant increase in the ICEF-5 index to 18.44 points on average, which indicates a decrease in the severity of erectile dysfunction from moderate to mild ( $p < 0.05$ ). Overall Tadalafil-SZ is an effective treatment for erectile dysfunction in both patients with prediabetes and patients with type 2 diabetes mellitus.

⊗ **Keywords:** erectile dysfunction; Tadalafil-SZ; prediabetes; type 2 diabetes mellitus.

## ЭФФЕКТИВНОСТЬ ТАДАЛАФИЛА-СЗ В ЛЕЧЕНИИ ЭРЕКТИЛЬНОЙ ДИСФУНКЦИИ У ПАЦИЕНТОВ С САХАРНЫМ ДИАБЕТОМ 2-ГО ТИПА И С ПРЕДИАБЕТОМ

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Цель настоящего исследования заключалась в оценке эффективности препарата Тадалафил-С3 в лечении эректильной дисфункции у мужчин с сахарным диабетом (СД) 2-го типа и преддиабетом. Под наблюдением находились 60 пациентов с СД 2-го типа ( $n = 30$ , средний возраст —  $52,2 \pm 3,4$  года) и преддиабетом ( $n = 30$ , средний возраст —  $48,5 \pm 2,8$  года). Все пациенты страдали эректильной дисфункцией, что существенно снижало качество их жизни. Для оценки эректильной функции использовали данные опросника Международного индекса эректильной функции (МИЭФ-5). Больные преддиабетом в качестве терапии эректильной дисфункции принимали Тадалафил-С3 по 5 мг 1 раз в день в течение 3 мес., а больные СД 2-го типа — Тадалафил-С3 по 20 мг 2 раза в неделю в течение 3 мес. Результаты исследования показали, что назначение Тадалафила-С3 больным обеих групп привело к существенному улучшению качества их жизни, снижению индекса массы тела, уменьшению объема талии, нормализации уровня гликированного гемоглобина без увеличения дозы сахароснижающей терапии у пациентов с неосложненным СД 2-го типа, у мужчин с преддиабетом отмечено выраженное снижение уровня инсулина в крови утром. Почти у половины пролеченных больных выявлено повышение содержания тестостерона в крови. Отмечено значительное улучшение эректильной функции: у пациентов с преддиабетом среднее значение индекса МИЭФ-5 повысилось с 18,68 до 23,02 балла ( $p < 0,05$ ), а у пациентов с СД 2-го типа — с 12,18 до 18,44 балла ( $p < 0,05$ ). Таким образом, Тадалафил-С3 является эффективным методом лечения эректильной дисфункции у пациентов с СД 2-го типа и преддиабетом.

**Ключевые слова:** эректильная дисфункция; Тадалафил-С3; преддиабет; сахарный диабет 2-го типа.

## INTRODUCTION

According to the World Health Organization (2017), diabetes mellitus (DM) is one of the most common diseases affecting men over the age of 40. Currently, the real challenge is the development of insulin resistance (prediabetes) among men in large Russian cities, which is associated with weight gain, primarily in the waist area; an insignificant increase in the levels of glucose, cholesterol, and uric acid in the blood; and an increase in blood pressure. The results of the long-term Massachusetts Male Aging Study showed that DM is one of the main risk factors for the development of erectile dysfunction (ED) [1], and according to some reports, up to 75% of men with DM suffer from ED [2]. G.A. Brunner et al. (1995) diagnosed ED in 49% and 89.2% of men with types 1 and type 2 DM, respectively [3]. J. Bancroft et al. (1996) determined the frequency of ED in DM types 1 and 2 as 35% and 59%, respectively [4].

ED occurs in more than 50% of patients with DM within the first 10 years from the onset of the disease. In older men, ED is usually the first clinical manifestation of DM [5]. Its presence leads to a significant decrease in the quality of life (QoL). The very possibility of ED in a DM patient worsens his mental condition, leading to deterioration in carbohydrate metabolism.

Until the 1990s, biogenic stimulants, adaptogens, vitamins, herbal medicinal products, and sedatives were widely used to treat ED. However, it was later revealed that the efficiency of such therapies exceeds insignificantly that of placebo and does not exceed 30%. During this period, intracavernous and intra-

urethral administration of certain drugs (phentolamine, papaverine, and prostaglandin E1), vacuum constrictor therapy, and vascular surgery (creating anastomoses) were developed, as well as penile prosthetics, since other therapeutic measures were ineffective [6].

Phosphodiesterase (PDE) type 5 inhibitors have revolutionized the treatment of ED. PDE type 5 inhibitors promote the relaxation of the smooth muscle tissue of the cavernous bodies by inhibiting the enzyme phosphodiesterase type 5 and increasing the concentration of cyclic guanosine monophosphate during sexual arousal, thus increasing blood flow to the cavernous bodies and contributing to the development and maintenance of physiological erection [7, 8]. Type 5 PDE inhibitors have a reversible effect. They are well tolerated by patients, can be used in elderly patients, and do not increase the risk of cardiovascular diseases [9, 10].

Currently, four drugs from the PDE type 5 inhibitors group are used in clinical practice, namely Sildenafil, Tadalafil, Vardenafil, and Udenafil. The pharmacokinetic profile of Tadalafil differs from that of Sildenafil, since the half-life of Tadalafil exceeds that of Sildenafil. The clinical effects of Tadalafil last for 36 hours after its administration, which gives a couple the opportunity to freely choose the time of intimacy [9, 11].

I. Eardley et al. (2005) studied the efficacy of Sildenafil and Tadalafil in 367 ED patients (mean age, 54 years) in a multicenter, randomized, crossover, open-label study. During treatment, 82% of men were able to penetrate successfully with the pe-

nis when treated with Sildenafil at a dose of 50–100 mg and 85% of men when treated with Tadalafil at a dose of 10–20 mg. A successful intercourse was noted in 72% of men who used Sildenafil and 77% of men who used Tadalafil. After the active treatment phase, the patients participated in the open phase of the study, during which 29% of them preferred further therapy with Sildenafil and 71% preferred Tadalafil [12].

D. Hatzichristou et al. (2008) in a 24-week multicenter randomized trial, studied the efficacy of a single daily use of Tadalafil at doses of 2.5 mg and 5 mg in DM patients with ED. Of 298 patients enrolled, 254 (85%) completed their participation in the study. Tadalafil, both at doses of 2.5 mg per day and 5 mg per day, was found to be more effective than placebo in all clinical parameters [13].

*This study aimed* to investigate the efficacy of Tadalafil-SZ in ED patients with type 2 DM and prediabetes (insulin resistance).

## MATERIALS AND METHODS

The study included 60 patients with type 2 DM (group 1,  $n = 30$ ; mean age,  $52.2 \pm 3.4$  years) and prediabetes (group 2,  $n = 30$ ; mean age,  $48.5 \pm 2.8$  years). We enrolled male patients with ED, aged over 40 years, who had type 2 DM that was confirmed to be in the stage of compensation or sub-compensation over the past 5 years, or those with metabolic disorders associated with hyperinsulinism (prediabetes).

The inclusion criteria of the type 2 DM patients were glycated hemoglobin level  $<7.2\%$ ; absence of DM complications (polyneuropathy, retinopathy, nephropathy, angiopathy) requiring constant main-

tenance therapy; hypoglycemic therapy limited only to metformin or diet; confirmed hypogonadism (testosterone level  $<12$  pmol/l); and confirmed ED.

The inclusion criteria for patients with prediabetes were confirmed hyperinsulinism (insulin level  $> 12.0$   $\mu\text{U/ml}$ ); absence of DM (glycated hemoglobin  $< 6.0\%$ ); body mass index  $> 25$   $\text{kg/m}^2$ ; waist circumference  $> 102$  cm; confirmed hypogonadism (testosterone level  $< 12$  pmol/l); and confirmed ED.

The study did not include patients with insulin-treated DM, confirmed DM complications, systemic chronic diseases requiring constant maintenance therapy, severe cardiovascular pathologies, lung and kidney diseases, and a high degree of obesity ( $\text{BMI} > 40$   $\text{kg/m}^2$ ).

Metformin was the main antihyperglycemic drug in patients with type 2 DM and prediabetes. Doses of the drug were determined individually. Metformin was taken by 78.2% of patients with type 2 DM and 7.2% of patients with prediabetes. During the follow-up period, all the patients with insulin resistance had their diet and physical activity adjusted.

Group 3 (control) consisted of 30 men aged above 25 years with a normal erectile function, who had no history of DM, no increase in blood insulin or glycated hemoglobin level, and a blood testosterone level  $>12.0$  pmol/l. The characteristics of the men in groups 1, 2, and 3 are presented in Table 1.

To assess the erectile function, a questionnaire survey was used according to the International Index of Erectile Function (IIEF-5). According to the IIEF-5 questionnaire, a score of 21–25 indicates the absence of ED, 16–20 indicate mild ED, 11–15 indicate moderate ED, and  $<10$  points indicate severe ED. The QoL of the patients was assessed using the QoL

Table 1 / Таблица 1

### Characteristics and clinical parameters of patients of 1, 2 and 3 patients groups ( $M \pm m$ )

#### Характеристика и клинические показатели больных 1, 2 и 3-й групп ( $M \pm m$ )

Indicator	Group 1 ( $n = 30$ )	Group 2 ( $n = 30$ )	Group 3 ( $n = 30$ )
Age, years	$52.2 \pm 3.4$	$48.5 \pm 2.8$	$46.2 \pm 4.2$
Duration of the disease, years	$5.6 \pm 1.2$	$2.8 \pm 0.6$	–
Body mass index, $\text{kg/m}^2$	$28.8 \pm 2.2$	$32.5 \pm 3.4$	$22.6 \pm 2.5$
Waist circumference, cm	$116.1 \pm 1.8$	$124.3 \pm 2.9$	$102.1 \pm 2.4$
Insulin, $\mu\text{U/ml}$	$17.8 \pm 2.2$	$32.4 \pm 3.6$	$7.5 \pm 1.6$
Glycated hemoglobin, %	$6.2 \pm 0.24$	$5.7 \pm 0.17$	$5.7 \pm 0.6$
Testosterone, pgmol/l	$4.2 \pm 0.8$	$5.1 \pm 0.5$	$16.2 \pm 0.7$
Antihyperglycemic therapy, %	78.2	7.2	–
Diet, %	54.3	34.7	–

questionnaire. Patients with type 2 DM (group 1) received Tadalafil-SZ 20 mg twice a week for three months as a therapy for ED, and patients with prediabetes (group 2) received Tadalafil-SZ 5 mg once a day for three months. After three months of treatment, the patients in groups 1 and 2 were examined repeatedly.

Data processing and analysis was performed using Microsoft Excel 2010 and the Statistica 6.0 statistical software package, respectively, with parametric and nonparametric statistical methods.

## RESULTS AND DISCUSSION

At the end of the treatment, the patients with type 2 DM (group 1) who received Tadalafil-SZ 20 mg twice a week had a tendency to lose weight and a decrease in body mass index, waist circumference, and blood insulin and glycated hemoglobin levels; moreover, these values became comparable with those of the men in group 3 (control) (Table 2). A similar tendency was noted in the group 2 patients with prediabetes, who received Tadalafil-SZ 5 mg once a day. They also showed a decrease in weight, body mass index, and blood insulin and glycosylated hemoglobin levels; nevertheless, their weight and waist circumference were significantly ( $p < 0.05$ ) higher than those of healthy individuals (Table 2). The insulin levels decreased most significantly, almost by half, within three months, which was apparently the main reason for the improvement in the QoL, erectile function, and weight loss. In addition, the efficiency of the treatment was undoubtedly associated with the use of Tadalafil-SZ, normalization of the eating behavior, and intake of metformin in individually selected doses.

When the patients in groups 1 and 2 were treated with Tadalafil-SZ, the blood testosterone level increased significantly, as in patients with

type 2 DM, from a baseline of  $4.2 \pm 0.8$  pmol/L to  $9.8 \pm 2.5$  pmol/L ( $p < 0.05$ ) in group 1 and  $5.1 \pm 0.5$  pmol/L to  $12.4 \pm 2.5$  pmol/L ( $p < 0.05$ ) in group 2. However, the testosterone levels in the patients of both treatment groups remained significantly lower than those in healthy patients of the control group ( $16.2 \pm 0.7$  pmol/L,  $p < 0.05$ ). Testosterone levels did not normalize equally in patients with type 2 DM and prediabetes. In group 1, an increase in testosterone levels was detected in 13 (43.3%) patients, and it remained unchanged in 17 (56.7%) patients. In group 2, an increase in testosterone levels was detected in 19 (63.3%) patients, and it remained unchanged in 11 (36.7%) patients.

We associate the increase in testosterone levels primarily to the decrease in blood insulin levels in the patients of both groups, which is accompanied by weight loss and normalization of erectile function. Nevertheless, Tadalafil-SZ intake significantly increases the blood testosterone level several men with carbohydrate disorders during the complex treatment, including the normalization of the eating behavior and use of erection modulators and drugs that normalize carbohydrate metabolism.

Patients in groups 1 and 2 who received Tadalafil-SZ showed a statistically significant improvement in erectile function according to the results obtained with the IIEF-5 questionnaire (Table 3). In the group 1 patients, the sum of points on the IIEF-5 scale before treatment averaged 12.18, and it increased significantly to 18.44 ( $p < 0.05$ ) by the end of treatment. In addition, moderate ED was diagnosed in 25 (83.3%) patients and mild ED in 5 (16.7%) patients before treatment. After treatment, 25 (83.3%) patients still had a mild ED, while 5 (16.7%) patients fully recovered their erectile functions ( $p < 0.05$ ). At the end of the treatment, 25 (83.3%) of 30 patients in group 1 had an adequate erection for pene-

Table 2 / Таблица 2

**The dynamics of the 1<sup>st</sup> and 2<sup>nd</sup> patients groups clinical parameters before and after treatment with Tadalafil-SZ ( $M \pm m$ )**  
**Динамика клинических показателей больных 1-й и 2-й групп до и после лечения Тадалафилом-СЗ ( $M \pm m$ )**

Indicator	Group 1 ( $n = 30$ )		Group 2 ( $n = 30$ )	
	before treatment	after treatment	before treatment	after treatment
Body mass index, kg/m <sup>2</sup>	$28.8 \pm 2.2$	$24.5 \pm 2.4$	$32.5 \pm 3.4$	$27.2 \pm 2.8$
Waist circumference, cm	$116.1 \pm 1.8$	$109.3 \pm 3.6$	$124.3 \pm 2.9$	$114.7 \pm 3.2$
Insulin, $\mu$ U/ml	$17.8 \pm 2.2$	$11.7 \pm 2.3^*$	$32.4 \pm 3.6$	$16.8 \pm 2.7^*$
Glycated hemoglobin, %	$6.2 \pm 0.24$	$5.8 \pm 0.4$	$5.7 \pm 0.17$	$5.5 \pm 0.9$
Testosterone, pgmol/l	$4.2 \pm 0.8$	$9.8 \pm 2.5^*$	$5.1 \pm 0.5$	$12.4 \pm 2.5^*$

Note. \* $p < 0.05$  compared to the indicator before treatment.

Table 3 / Таблица 3

**Dynamics of the IIEF-5 questionnaire total score in patients of the 1<sup>st</sup> and 2<sup>nd</sup> groups before and after treatment with Tadalafil-SZ ( $M \pm m$ )****Динамика суммы баллов по опроснику МИЭФ-5 у пациентов 1-й и 2-й групп до и после лечения Тада-лафилом-СЗ ( $M \pm m$ )**

IIEF 5 question	Group 1 (n = 30)		Group 1 (n = 30)	
	before treatment (points)	after treatment (points)	before treatment (points)	after treatment (points)
1. How do you rate your confidence that you could get and keep an erection?	2.64 ± 0.14	3.77 ± 0.14*	3.08 ± 0.14	4.72 ± 0.07*
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	2.19 ± 0.16	3.80 ± 0.11*	3.10 ± 0.21	4.30 ± 0.16*
3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	2.16 ± 0.09	3.63 ± 0.19*	4.34 ± 0.18	4.5 ± 0.11
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	2.35 ± 0.17	3.76 ± 0.14*	4.05 ± 0.14	4.77 ± 0.2*
5. When you attempted sexual intercourse, how often was it satisfactory for you?	2.84 ± 0.11	3.48 ± 0.16*	4.11 ± 0.12	4.73 ± 0.27*

Note. \* $p < 0.05$  compared to the indicator before treatment.

tration of the penis into the vagina. Erection persisted throughout the sexual intercourse in 22 (73.3%) patients. In the group 2 patients, the sum of points on the IIEF-5 scale before the start of Tadalafil-SZ administration averaged 18.68, and by the end of treatment, it increased to an average of 23.02 points ( $p < 0.05$ ). Before treatment, mild ED was diagnosed in 26 (86.7%) patients and moderate ED in 4 (13.3%) patients. After treatment, 26 patients had no erectile dysfunction, and 4 patients had mild ED ( $p < 0.05$ ). At the end of the treatment, 27 (90%) patients reported having complete satisfaction from intercourse, and 25 (83.3%) patients in this group indicated the ability to maintain erection throughout the intercourse.

Improvement of erectile function during the treatment with Tadalafil-SZ, assessed using the IIEF-5 scale, was accompanied by a significant improvement in the QoL of the patients. When interpreting the results of the QoL assessment, an increase in the QoL by 20% or more was considered as a pronounced positive effect, while an increase in the QoL by less than 20% was regarded as a moderate improvement. Pronounced improvement in the QoL was noted in 15 (50%) patients of group 1 and 26 (86.7%) patients of group 2; moderate improvement was registered in 15 (50%) patients of group 1 and 4 (13, 3%) patients of group 2. In the course

of treatment with Tadalafil-SZ, none of the patients had deterioration in the QoL, but all of them had a positive effect.

## CONCLUSION

This study revealed that the drug Tadalafil-SZ is effective in treating the ED of patients with prediabetes and type 2 DM. Due to the treatment, the QoL is significantly improved. The use of Tadalafil-SZ in the complex treatment of ED in patients with type 2 DM and prediabetes is accompanied by weight loss, normalization of carbohydrate metabolism without an increase in antihyperglycemic therapy, and a significant increase in blood testosterone levels.

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