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OPTIMIZATION THE TREATMENT OF MOTOR FLUCTUATIONS IN VARIOUS FORMS OF PARKINSON'S DISEASE

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Levodopa is one of the most effective drugs for the treatment of Parkinson's disease. However, the use of high doses of the drug has many adverse effects. Motor complications of levodopa, in the form of motor fluctuations and dyskinesia, occur in 30 to 40 percent of during the first five years of use and nearly 60 percent or more by 10 years.

In the course of the study, an assessment of groups of patients with various forms of Parkinson's disease – akinetic-rigid and mixed, the nature of motor fluctuations, analysis of the relationship with the duration of the disease, levodopa therapy, drug dosage was carried out. Schemes for the treatment of motor fluctuations due to taking levodopa drugs in short-acting and long-acting drugs were analyzed. A positive effect was found in the form of a total intake of levodopa drugs.

We can recommend to consider adding of long-release levodopa for management of motor complications in Parkinson's disease patients with rigidity and akinetic-rigid and tremor-dominant forms of Parkinson's disease.

A proposed regimen for the addition of sustained-release levodopa for the treatment of motor complications in patients with various forms of Parkinson's disease.

Key words: *Parkinson's disease, motor fluctuations, optimization of treatment.*

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Introduction. Levodopa is one of the most effective drugs for the treatment of Parkinson's disease (PD), and is the gold standard for the treatment of the disease [1]. However, the use of high doses of the drug has many adverse effects. Motor fluctuations and dyskinesia are important complications of levodopa therapy that affect many patients with PD [2].

The etiology of motor fluctuations is multifactorial. As Parkinson's disease progresses, the degeneration of nigrostriatal dopaminergic neurons continues [3]. As a result, presynaptic neurons lose their ability to store and release levodopa after enzymatic conversion to dopamine. As a result, the response to exogenous levodopa begins to reflect its short half-life (90 minutes). The rapid cycling kinetics and pulsatile stimulation of dopamine receptors by dopamine may contribute to a narrowing of the therapeutic window over time. An additional factor is that absorption of levodopa in the small intestine is highly dependent on proper intestinal absorption, which can be impaired by a number of factors, including poor gastric emptying, slow intestinal transit time, competing dietary protein, and small intestinal bacterial overgrowth [4].

When levodopa therapy is first instituted, patients with PD typically experience a smooth and prolonged response. However, as the disease advances, the effect of levodopa begins to wear off three to four hours after a dose. Motor complications of levodopa, in the form of motor fluctuations and dyskinesia, occur in 30 to 40 percent of patients during the first five years of use and nearly 60 percent or more by 10 years [5].

Motor fluctuations represent changes between periods of increased response to levodopa and periods when the response to levodopa disappears [6]. Types of motor oscillations include:

1. "Wearing" of the dose is the recurrence of symptoms of the disease, when the effect of levodopa decreases near the end of the interval between doses, usually three to four hours after taking the dose. The phenomenon of "wearing out" is often the first and most common fluctuation in patients with Parkinson's disease.

2. Unpredictable "off" periods that do not depend on the time of taking levodopa and the appearance of "exclusion" episodes.

3. Stiffness during gait, in which the patient cannot move forward, moving forward, the limbs seem to freeze in one position, the patient stops, everything slows down, despite the intention to walk. It is one of the most debilitating motor symptoms in patients with PD and can lead to falls and loss of independence.

4. Failure of the turn-on response with no or no turn-on response after a dose of levodopa.

5. Acute akinesia is a sudden, severe exacerbation involving an akinetic state that lasts for several days and does not respond to treatment with antiparkinsonian drugs.

Another manifestation of the side effects of levodopa is dyskinesias, which resemble various involuntary movements, including chorea, dystonia, ballism and myoclonus [7], occur at different times depending on the dose of levodopa. Among dyskinesias are very common:

1. Peak dyskinesia appears during the patient's turn-on period and resembles chorea.

2. Biphasic dyskinesia results in two separate periods of involuntary movements after a dose of levodopa – on and off. dyskinesia" below.)

3. Wear-out dystonia occurs at shutdown and manifests as dystonia, often involving the extremities, but may also extend to the face, neck, or trunk.

Depending on the most prominent symptom and the baseline medication regimen, a variety of pharmacologic strategies can be used to manage motor complications.

The aim of our study was to determine the nature of motor fluctuations and optimize the treatment approach

for various forms of Parkinson's disease.

Object and methods of the research. We examined 80 patients with Parkinson's disease who were undergoing examination and inpatient treatment in the neurological department of the Poltava Regional Clinical Hospital named after M.V. Sklifosovsky and on the basis of the Center for patients with Parkinson's disease and other neurodegenerative diseases on the basis of the Department of Nervous Diseases of the Poltava State Medical University.

In the course of the study, we evaluated the age, duration of the disease, duration of therapy with levodopa drugs, dose of levodopa drugs, frequency and nature of motor fluctuations.

The diagnosis was established according to the criteria of the World Brain Bank of Great Britain. The degree of clinical manifestations was determined by the unified rating scale of Parkinson's disease assessment modified by the International Parkinson's Disease and Movement Disorders Society (MDS-UPDRS) and the Hoehn and Yahr scale. The degree of assessment of daily activity was carried out according to the scale of Schwab and England. To assess motor fluctuations and dyskinesias, the patient's diary was used, which the patient filled out on his own for 3 days before the visit to the clinic. According to the diary, the duration of the "off period" was determined against the background of treatment.

Patients, depending on the prevalence of symptoms, were divided into groups:

Group 1 – 40 patients with akinetic-rigid form (AR);

Group 2 – 40 patients with a mixed akinetic-rigid-tremor (ART) form.

All patients included in the study were treated with levodopa drugs. Depending on levodopa therapy, patients of both groups were divided into subgroups.

Patients of the both groups are divided into following subgroups:

a subgroup – patients received therapy with short-acting levodopa drugs 4 times a day.

b subgroup – patients received combined short-acting levodopa 3 times per day with extended-acting levodopa before sleep.

The criteria for inclusion in the study were: an inserted diagnosis of Parkinson's disease, 27-30 points on a short scale for assessing cognitive functions (Mini-Mental State Examination), treatment with levodopa drugs for more than 3 years, the presence of motor fluctuations.

Exclusion criteria were: secondary parkinsonism, "parkinsonism-plus", CP stage on the Hehn and Yahr scale greater than 4, cerebrovascular diseases, age 90 years and older.

Statistical analysis was performed by IBM SPSS Statistics 26.0. According to the normality of the distribution by Shapiro-Wilk test, we used parametric or non-parametric methods. Quntitative data was shown as means (M) and standard error (σ), while qualitative ones as absolute amount (abs.) and percent (%). We have used t-test for independent samples and χ^2-criteria with Yates correction. Critical p-value was 0.05.

Table 1 – Characteristics of patients with various forms of Parkinson's disease on the background of taking levodopa, (M±σ)

Indicators	Patients with PD n=80)	Group 1 (n=40)	Group 2 (n=40)	p-value
Age (years)	63.6±4.9	62.3±4.7	64.8±5.1	0.452
Sex	Male 52 (65%) Female 28 (35%)	Male 25 (62.5%) Female 13 (32.5%)	Male 27 (67.5%) Female 15 (37.5%)	0.684
Duration of illness (months)	70.7±6.9	72.7±6.2	68.6±7.6	0.385
Duration of levodopa therapy (months)	51.4±10.5	52.8±9.3	49.9±11.6	0.108
Levodopa daily dose (mg)	555.7±140.5	580.4±160.7	530.9±120.4	0.041*
Hoenh and Yahr	3.7±0.8	3.7±0.7	3.6±0.9	0.703
UPDRS-I	2.85±1.1	2.8±1.3	2.9±0.8	0.362
UPDRS-II	12.6±7.3	12.9±6.5	13.2±11.2	0.741
UPDRS-III (off)	35.1±10.2	33.7±11.4	28.4±12.4	0.025*
UPDRS-IV	4.7±1.2	3.2±1.3	2.8±0.8	0.044*
Duration «off» periods (hours)	2.45±1.05	3.1±1.2	1.8±0.9	0.002
Schwab and England	85.12±5.69	78.29±9.84	88.13±7.51	0.027*

Notes: * – p-value is less than critical 0.05 by t-test.

Research results and their discussion. The average age of the patients was 63.6±4.9 years, the average duration of Parkinson's disease was 70.7±6.9 months, the average duration of levodopa treatment was 51.4±10.5 months. The average daily dose of levodopa in group of patients was 555.7±140.5 mg. One of the complications of levodopa therapy is the appearance «off» periods. These episodes may present with either motor or non-motor symptoms or a combination.

Motor complications of therapy were assessed by the Unified Parkinson's Disease Rating Scale-IV and by 3-day diaries of motor state, which the patients filled out for several days before the doctor's examination.

In order to correct motor fluctuations in groups of patients, correction of diet and levodopa medication was performed as a priority. Absorption of levodopa in the duodenum and its transport across the blood-brain barrier is facilitated by a large neutral amino acid transporter protein. The ingested protein competes with the transport of levodopa in the intestine and brain, thereby reducing the clinical benefit of levodopa [8].

All patients were instructed to avoid protein intake while taking the drug and/or to take the drug on an empty stomach, 30–60 minutes before or 60–90 minutes after a meal.

The main characteristics of patients in subgroups of patients are presented in **table 1**.

It was shown that group 1 had higher average daily levodopa doses, increased motor deficits and more motor complications compare to group 2. On the other hand, group 1 had lower score by Schwab and England scale compare to group 2. It demonstrates that patients with AR form has more severe motor disturbances and lower level of independence. These differences cause finding method for optimization of treatment with considering motor forms of PD.

Motor complications in patients with various forms of PD contains "wearing" off, unpredictable off periods, freezing, insufficient "inclusion" **(table 2)**.

We have not found any differences in the frequency of different types of motor complications between groups (p=0.631).

For correction of motor fluctuations, namely off periods, patients were divided into subgroups. Patients of the first group are divided into: 1a subgroup received therapy with short-acting levodopa drugs 4 times a day. Daily dose 560.5±130.5 mg.

Subgroup 1b, while taking short-acting levodopa 4 times a day, received levodopa retard therapy 3 times a day (2 times during a day short-acting levodopa drugs and 1 intake before night). The daily dose of levodopa was 610.3±62.5 mg.

Table 2 – The frequency of motor fluctuations in groups of patients with various forms of Parkinson's disease on the background of taking levodopa, abs. (%)

Type of motor fluctuations	Groups	
	Group 1 (n=40)	Group 2 (n=40)
«Wearing» off	12 (30%)	14 (35%)
Unpredictable off periods	10 (25%)	11 (28%)
Freezing	13 (33%)	8 (20%)
Insufficient «inclusion»	5 (12%)	7 (17%)

Group 2 patients with a mixed form of the disease were also divided into 2 subgroups: 2a – patients receiving short-acting levodopa 4 times a day. Daily dose 520.5±125.0 mg, subgroup 2b – combined short-acting levodopa with extended-acting levodopa 2 times a day during a short-acting levodopa drugs and 1 intake before night). Daily dose 540.5±115.0 mg.

Against the background of treatment with the use of long-acting levodopa in subgroups of patients with AR and ART forms, positive changes were observed in the form of a decrease in the frequency of movement disorders in comparison with subgroups of patients treated only with levodopa drugs. A decrease in the frequency of motor fluctuations was observed in the groups of patients receiving prolonged levodopa therapy against the background of short-acting levodopa treatment **(table 3)**.

Table 3 – The frequency of motor fluctuations in subgroups of patients with Parkinson's disease on the background of treatment with the use of levodopa of prolonged action abs. (%)

Type of motor fluctuations	Group 1 (n=40)		Group 2 (n=40)	
	1a (n=20)	1b (n=20)	2a (n=20)	2b (n=20)
«Wearing» off	7 (35%)	2 (10%)	4 (20%)	2 (10%)
Unpredictable off periods	10 (50%)	6 (30%)	12 (60%)	4 (20%)
Freezing	12 (60%)	5 (25%)	9 (45%)	3 (15%)
Insufficient «inclusion»	7 (35%)	3 (15%)	6 (30%)	2 (10%)

It was shown that in group 1 frequency of "wearing" off (p=0.058), unpredictable off periods (p=0.197) and insufficient "inclusion" (p=0.144) were not differ between subgroups. At the same time, the frequency of freezing was lower in subgroup 1b compare to subgroup 1a (χ^2=5.01, p=0.025). In group 2 frequencies of "wearing" off (p=0.376) and insufficient "inclusion" (p=0.114) have not statistically significant differences between subgroups. The frequency of unpredictable off periods (χ^2=6.67, p=0.009) and freezing (χ^2=4.29, p=0.038) was lower in subgroup 2b than in subgroup 2a.

The following changes were observed regarding the clinical manifestations and duration of the off period **(table 4)**.

Table 4 – Clinical features of subgroups of patients with various forms of Parkinson's disease against the background of different treatment regimens, (M±σ)

Indicators	Group 1 (n=40)		Group 2 (n=40)	
	1a (n=20)	1b (n=20)	2a (n=20)	2b (n=20)
Levodopa daily dose (mg)	560,5±130,5	610,3±62,5	520,5±125,0	540,5±115,0
Hoenh and Yahr	3,2±0,7	3,4±0,2	3,4±0,7	3,3±0,2
UPDRS-I	2,8±1,3	1,7±0,5	2,9±0,8	1,9±0,7
UPDRS-II	12,9±6,5	11,4±4,8	13,2±11,2	10,1±3,4
UPDRS-III (off)	33,7±11,4	28,4±10,6*	28,4±12,4	24,1±9,8**
UPDRS-IV	3,2±1,3	2,0±1,6	2,8±0,8	2,1±0,9
Duration «off» periods (hours)	3,1±1,2	1,6±1,1*	1,8±0,9	1,1±0.8
Schwab and England	78,29±9,84	86,19±8,66*	88,13±7,51	87,29±8,54

Notes: * – p-value is less than critical 0.05 by t-test compare to subgroup 1a, **- p-value is less than critical 0.05 by t-test compare to subgroup 2a.

It was shown that in patients with AR form combined therapy significantly decreased duration "off" period (p=0.029), improved UPDRS-III (p=0.007) and Schwab and England scores (p=0.038), when in group with ART form it only decreases UPDRS-III score (p=0.014).

Three randomized control trials provide evidence for the efficacy, safety and tolerability of extended release carbidopa-levodopa in patients with both early and advanced Parkinson's disease [9].

The primary goal of prescription long-release levodopa drugs is not to dramatically decrease the levodopa dosing frequency, even though such a reduction may improve convenience and adherence and might also facilitate the timing of doses away from meals to reduce competition with dietary protein for intestinal absorption. The primary goal is to raise the troughs and lower the peaks in plasma levodopa level, so as to minimize motor fluctuations and peak-dose dyskinesia [10].

Neurophysiological research suggests that the complications may be an outcome of long-term non-physiological pulsatile fluctuations in levodopa concentrations associated with dosing of conventional oral levodopa products [11]. Our results support that combined therapy with long-release levodopa may improve motor complications, especially in patients with AR form of PD.

Conclusions. In the course of the treatment, a significant improvement in the clinical symptoms and reduction of motor complications were observed in PD patients receiving treatment using combined levodopa therapy (a combination of short-acting levodopa and long-acting levodopa). we have shown better response for changing treatment strategy in patients with AR forms of PD. Thus, we can recommend to consider adding of long-release levodopa for management of motor complications in PD patients with AR and ART forms of PD.

Prospects for further research. Further research should be aimed at the analysis and optimization of measures for the correction of non-motor fluctuations, which significantly affect the quality of life of patients with various forms of Parkinson's disease. The development of a levodopa formulation capable of delivering more stable plasma concentrations is therefore a major need for PD management.

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ОПТИМІЗАЦІЯ ЛІКУВАННЯ РУХОВИХ ФЛУКТУАЦІЙ РІЗНИХ ФОРМ ХВОРОБИ ПАРКІНСОНА

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Резюме. Леводопа є золотим стандартом лікування хвороби Паркінсона. Рухові флуктуації та дискінезія є важливими ускладненнями терапії леводопою, які вражають багатьох пацієнтів із хворобою Паркінсона.

Метою нашого дослідження було визначити характер рухових флуктуацій та оптимізувати тактику лікування різних форм хвороби Паркінсона.

Обстежено 80 хворих на хворобу Паркінсона, які перебували на обстеженні та стаціонарному лікуванні в неврологічному відділенні Полтавської обласної клінічної лікарні імені М.В. Скліфосовського та на базі Центру для хворих на хворобу Паркінсона та інші нейродегенеративні захворювання на базі кафедри нервових хвороб Полтавського державного медичного університету. Усі пацієнти, включені в дослідження, отримували лікування препаратами леводопи. Залежно від терапії леводопою пацієнти були розподілені на підгрупи: підгрупа – пацієнти отримували терапію препаратами леводопи короткої дії 4 рази на добу. б підгрупа – пацієнти отримували перед сном комбінацію леводопи короткої дії 3 рази на добу з леводопою пролонгованої дії.

У хворих з акінетико-ригідною формою виражені рухові порушення та нижчий рівень самостійності. Ці відмінності зумовлюють пошук методу оптимізації лікування з урахуванням рухових форм хвороби Паркінсона. Серед рухових ускладнень, що зустрічаються у хворих на різні форми хвороби Паркінсона, переважали: феномен «зношування», непередбачувані періоди виключення, завмирання, недостатнє «включення».

Показано, що у хворих із акінетико-ригідною формою комбінована терапія достовірно зменшує тривалість періоду «вимкнення», покращує показники (UPDRS-III) та Шваба та Інгланда, тоді як у групі з акінетико-ригідно-тремтячою формою лише знижує показник UPDRS-III.

У процесі лікування у хворих на хворобу Паркінсона, які отримували комбіновану терапію леводопою (комбінація леводопи короткої дії та леводопи тривалої дії), спостерігалося значне покращення клінічних симптомів та зменшення моторних ускладнень. ми показали кращу відповідь на зміну стратегії лікування у пацієнтів з ригідними формами захворювання. Ми можемо рекомендувати розглянути можливість додавання леводопи тривалого вивільнення для лікування рухових ускладнень у пацієнтів із хворобою Паркінсона з ригідністю та акінетико-ригідно -тремтячою формами хвороби Паркінсона.

Ключові слова: Хвороба Паркінсона, моторні флуктуації, оптимізація лікування.

OPTIMIZATION THE TREATMENT OF MOTOR FLUCTUATIONS VARIOUS FORMS OF PARKINSON'S DISEASE

Tarianyk K. A., Lytvynenko N. V., Purdenko T. Y., Sylenko H. Y.

Abstract. Levodopa is the gold standard for the treatment of Parkinson's disease. Motor fluctuations and dyskinesia are important complications of levodopa therapy that affect many patients with Parkinson's disease.

The aim of our study was to determine the nature of motor fluctuations and optimize the treatment approach for various forms of Parkinson's disease.

We examined 80 patients with Parkinson's disease who were undergoing examination and inpatient treatment in the neurological department of the Poltava Regional Clinical Hospital named after M.V. Sklifosovsky and on the basis of the Center for patients with Parkinson's disease and other neurodegenerative diseases on the basis of the Department of Nervous Diseases of the Poltava State Medical University. All patients included in the study were treated with levodopa drugs. Depending on levodopa therapy, patients were divided into subgroups: a subgroup – patients received therapy with short-acting levodopa drugs 4 times a day. b subgroup – patients received combined short-acting levodopa 3 times per day with extended-acting levodopa before sleep.

The patients with akinetic-rigid form has more severe motor disturbances and lower level of independence. These differences cause finding method for optimization of treatment with considering motor forms of Parkinson's disease. Among the motor complications encountered in patients with various forms of Parkinson's disease, the following prevailed: the phenomenon of "wearing out", unpredictable periods of disconnection, freezing, insufficient "switching on".

It was shown that in patients with rigidity form combined therapy significantly decreased duration "off" period, improved UPDRS-III) and Schwab and England scores, when in group with akinetic-rigidity-tremor form it only decreases UPDRS-III score.

In the course of the treatment, a significant improvement in the clinical symptoms and reduction of motor complications were observed in Parkinson's disease patients receiving treatment using combined levodopa therapy (a combination of short-acting levodopa and long-acting levodopa). we have shown better response for changing treatment strategy in patients with rigidity forms of disease. We can recommend to consider adding of long-release levodopa for management of motor complications in Parkinson's disease patients with rigidity and akinetic-rigid and tremor-dominant forms of Parkinson's disease.

Key words: Parkinson's disease, motor fluctuationы, optimization of treatment.

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SURGICAL TREATMENT OF RECURRENCE OF PILONIDAL CYSTS OF THE SACROCOCCYGEAL AREA USING CROSS-LINKED POLYURETHANE ADHESIVE AND IZOTRETINOIN

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The attempts to address the issue of recurrence rate are aimed at finding an effective surgical technique, but these methods are becoming more and more traumatic, involving not only the intergluteal folds, where the main pathological focus is located, but also a significant part of the surrounding buttocks. The aim of the work was to improve the results of treatment of patients with recurrent pilonidal cysts of the sacrococcygeal area through complex surgical treatment using cross-linked polyurethane adhesive and isotretinoin.

The analysis of surgical treatment of 120 patients with recurrence of pilonidal cyst of the sacrococcygeal area was carried out. The age of the patients ranged from 18 to 46 years. The patients were divided into 2 groups depending on the method of treatment. In group 1 (60 patients), surgical treatment was carried out according to the method of economical median resection developed by the authors with double-row internal extraepidermal sutures in combination with a cross-linked polyurethane adhesive. All patients of this group were prescribed isotretinoin at a dose of 0.5 mg/kg/. In group 2 (60 patients), surgical treatment of pilonidal cysts was performed using the traditional method of median resection.

Surgical treatment of patients with recurrence of pilonidal cysts of the sacrococcygeal area using the developed method in combination with adhesive composition based on cross-linked polyurethane and isotretinoin provides significantly better efficacy compared to traditional method, namely reduces the incidence of postoperative complications: hematoma to 0% vs. 1.7%, seroma to 5% vs. 21.7%, wound infection to 0% vs. 5%, recurrence to 0% vs. 15%.

Key words: *pilonidal cyst, midline resection, isotretinoin, recurrence of pilonidal cyst.*