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Therapeutic physical factors as part of outpatient medical rehabilitation for patients after colorectal cancer surgery: a randomized controlled trial

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ABSTRACT

BACKGROUND: The comprehensive use of therapeutic physical factors in rehabilitation programs contributes to improving the effectiveness of therapeutic measures by favorably influencing sanogenesis processes.

AIM: To evaluate the effectiveness of an outpatient medical rehabilitation program for patients after colorectal cancer surgery using therapeutic physical factors.

MATERIALS AND METHODS: An open-label, randomized, controlled prospective study included 126 patients who underwent colorectal cancer surgery. Using simple randomization, the patients were divided into three groups. In Comparison group 1 (n=40), rehabilitation followed the Russian guidelines (individual therapeutic exercise and pinaverium bromide). In Comparison group 2 (n=43), in addition to the rehabilitation measures of Group 1, patients received low-mineralized mineral water "*Psyz*." In the Main group (n=43), patients received transcutaneous electrical nerve stimulation in the area of the cervical sympathetic ganglia in addition to Group 2 rehabilitation program. The effectiveness of rehabilitation measures was assessed using clinical symptom evaluation based on the Edmonton Symptom Assessment System (ESAS) and quality of life assessment with the European Quality of Life Questionnaire (EQ-5D).

RESULTS: Statistical analysis demonstrated that incorporating therapeutic physical factors into outpatient medical rehabilitation programs for patients after colorectal cancer surgery significantly reduced clinical symptoms according to the ESAS scale (p <0.01) and improved quality of life indicators according to the EQ-5D scale, particularly in the Daily Activities (p <0.01), Pain and Discomfort (p < 0.01), and Anxiety and Depression (p <0.01) domains. Meanwhile, the positive changes in the studied parameters were, on average, 12–15% lower (p <0.05) in Comparison group 1 and 8–10% lower in Comparison group 2 compared with the Main group.

CONCLUSION: The inclusion of therapeutic physical factors in outpatient medical rehabilitation programs for patients after colorectal cancer surgery leads to a significant improvement in quality of life.

Keywords: colorectal cancer; outpatient medical rehabilitation; therapeutic physical factors.

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Лечебные физические факторы в программах амбулаторной медицинской реабилитации пациентов после оперативного вмешательства по поводу колоректального рака (рандомизированное контролируемое исследование)

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АННОТАЦИЯ

Актуальность. Комплексное применение лечебных физических факторов в программах восстановительного лечения способствует повышению эффективности терапевтических мероприятий за счёт их благоприятного воздействия на процессы саногенеза.

Цель исследования — оценить эффективность программы амбулаторной медицинской реабилитации пациентов после оперативного вмешательства по поводу колоректального рака с применением лечебных физических факторов.

Материалы и методы. В открытое рандомизированное контролируемое проспективное исследование включены 126 пациентов после оперативного вмешательства по поводу колоректального рака. С использованием метода простой рандомизации пациенты распределены в три группы. В 1-й группе сравнения (n=40) пациенты получали реабилитацию в соответствии с российскими клиническими рекомендациями (индивидуальная лечебная физкультура, пинаверия бромид); во 2-й группе сравнения (n=43) пациентам дополнительно к реабилитационным мероприятиям 1-й группы сравнения назначена маломинерализованная минеральная вода «Псыж»; в основной группе (n=43) пациенты к реабилитационному комплексу 2-й группы сравнения получали чрескожную электронейростимуляцию на область шейных симпатических ганглиев. Контроль эффективности реабилитационных мероприятий проведён методом оценки клинических симптомов по Эдмонтонской системе (ESAS) и качества жизни по опроснику European Quality of Life Questionnaire (EQ-5D).

Результаты. Проведённый статистический анализ показал, что включение лечебных физических факторов в программы амбулаторного этапа медицинской реабилитации пациентов после оперативного вмешательства по поводу колоректального рака способствовало значимому редуцированию клинических симптомов по ESAS (p <0,01), улучшению показателей качества жизни по EQ-5D, более всего по шкалам «Повседневная активность» (p <0,01), «Боль и дискомфорт» (p <0,01) и «Тревога и депрессия» (p <0,01), при этом положительная динамика изученных показателей у пациентов 1-й группы сравнения была ниже в среднем на 12–15% (p <0,05), во 2-й группе сравнения — на 8–10%.

Заключение. Включение лечебных физических факторов в программы медицинской реабилитации пациентов после оперативного вмешательства по поводу колоректального рака на амбулаторном этапе медицинской реабилитации обеспечивает значимое улучшение качества жизни.

Ключевые слова: колоректальный рак; амбулаторная медицинская реабилитация; лечебные физические факторы.

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结直肠癌手术后患者门诊医学康复方案中治疗性物理因子的应用（随机对照研究）

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摘要

背景。在康复方案中综合应用治疗性物理因子，有助于改善治疗措施的效果，并通过积极影响机体的自愈过程促进康复。

目的。评估在结直肠癌手术后患者的门诊医学康复方案中应用治疗性物理因子的有效性。

材料与方法。本开放性、随机对照、前瞻性研究共纳入126例结直肠癌手术后患者，通过简单随机化方法分为三组。 第一对照组（*n*=40）— 依据俄罗斯临床指南进行康复治疗，包括个性化治疗体操及匹维溴铵治疗；第二对照组（*n*=43）— 在第一组康复方案基础上，额外接受低矿化矿泉水“Psyz”治疗；实验组（*n*=43）— 在第二组康复方案基础上，额外接受颈交感神经节区域的经皮神经电刺激。康复效果通过爱德蒙顿症状评估系统（Edmonton Symptom Assessment System，ESAS）进行临床症状评估，并使用欧洲生活质量问卷（European Quality of Life Questionnaire，EQ-5D）评估生活质量变化。

结果。统计分析表明，在结直肠癌手术后患者的门诊康复方案中加入治疗性物理因子，能显著减少ESAS评分中的临床症状（p <0.01），并改善EQ-5D评估的生活质量指标，尤其是在：“日常活动”（p <0.01），“疼痛与不适”（p < 0.01），“焦虑与抑郁”（p <0.01）。相比之下：第一对照组患者的上述指标改善幅度平均低12–15%（p <0.05）；第二对照组患者的改善幅度低8 — 10%。

结论。在结直肠癌手术后患者的门诊医学康复方案中加入治疗性物理因子，能够显著提高患者的生活质量。

关键词：结直肠癌；门诊医学康复；治疗性物理因子。

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BACKGROUND

In Russia, as worldwide, there is an increasing incidence of cancer, including gastrointestinal malignancies, occupying leading positions in the mortality structure of malignant neoplasms [1–4]. According to Kaprin [1], the prevalence of colorectal cancer in Russia increases by 3–4% annually, with the colon cancer accounting for 7.1% of malignant neoplasms in the morbidity structure. Osombaev et al. [5] classify Russia among countries with growing or stable incidence and mortality rates for colon cancer (colorectal cancer).

For localized and locally advanced colorectal cancer (T1-3N0M0), surgical treatment (right/left hemicolectomy, lymph node dissection) is recommended, followed by rehabilitation to facilitate recovery of impaired body functions, including the patient's mental functioning [6–8]. Overall, according to Krutov et al. [6], medical rehabilitation for patients after surgical intervention for colorectal cancer should be conducted in accordance with the fast-track surgery concept and aimed at alleviating pain syndrome, increasing patient activity, restoring intestinal peristalsis, and stabilizing emotional status. In this context, therapeutic physical modalities with sanogenetic effects appears appropriate [9–14]. Specifically, therapeutic exercise helps enhance the body's adaptive capabilities through gradually increasing physical activity [15]. Low-mineralization drinking mineral waters stimulate patients to increase functional reserves of both stress-mobilizing and stress-limiting systems, which is particularly important in the postoperative period [11, 16]. Furthermore, course treatment with oral mineral water consumption exerts colon-stimulating and colon-modulating therapeutic effects [16, 17].

In recent years, percutaneous electrical nerve stimulation (PENS) has been widely used in medical rehabilitation, demonstrating effectiveness in alleviating pain syndrome, improving metabolic processes, microcirculation, peripheral nerve conductivity, and other therapeutic benefits in patients [11, 18, 19]. The well-documented myorelaxant, spasmolytic, trophic, and vegetocorrective effects (when applied to sympathetic ganglia) of PENS significantly expand its clinical applications. For instance, studies by Al-Zahmil et al. [16] have shown that PENS contributes to motor deficit regression and reduced muscle atrophy severity in patients with syringomyelia-associated amyotrophic lateral sclerosis. Research of Kaisinova et al. [18] has demonstrated that low-frequency pulsed electrical nerve stimulation in health-resort treatment of chronic pancreatitis demonstrated analgesic, anti-inflammatory, and spasmolytic therapeutic effects. Studies by Law et al. [19] of PENS for joint pathology reported not only pain relief but also substantial improvement in joint function.

It is hypothesized that incorporating physical therapeutic factors into outpatient rehabilitation programs for patients after surgical intervention for colorectal cancer will have a positive impact on improving the motor-evacuatory function of the large intestine, reducing the severity of anxiety-depressive disorders, and restoring quality of life (QoL).

The study aimed to evaluate the effectiveness of an outpatient medical rehabilitation program for patients after colorectal cancer surgery using therapeutic physical factors.

METHODS

Study Design

This was a prospective randomized controlled clinical study.

Eligibility Criteria

Inclusion criteria: status after left-/right-sided hemicolectomy (or sigmoid colon resection) for colorectal cancer without regional lymph node involvement or metastasis (T_1-$T_3N_0M_0$); 3–6 months post-surgery; patient condition assessment score of 3 points on the rehabilitation routing scale; informed voluntary consent.

Non-inclusion criteria: stage IV–V colon cancer; acute-phase and/or decompensated somatic diseases; general contraindications to physical therapy; general contraindications to therapeutic exercise.

Exclusion criteria: sudden deterioration of the patient's general health; patient's refusal to participate in the study.

Study Setting

The study was conducted in outpatient clinics of the Karachay-Cherkess Republic in accordance with ethical principles (Helsinki Declaration, Brazil 2013).

Study Duration

The study was conducted from January 2021 to June 2024.

Intervention

The study participants (n = 126) were divided into three groups comparable in sex, age, disease stage, and severity. In comparison group 1 (n = 40), patients received rehabilitation according to Russian clinical guidelines: diet therapy (a standard mechanically and chemically sparing diet); individual physical therapy sessions lasting 25 minutes (10 sessions per treatment course); small-group psychotherapy sessions lasting 30 minutes daily (8 sessions per treatment course); and the spasmolytic agent pinaverium bromide (France) at 10 mg (1 tablet 3 times daily 30 minutes before meals for 1 month).

In comparison group 2 (n = 43), patients received additional rehabilitation beyond those in group 1: Psyzh chloride-sulfate sodium-magnesium mineral water (Karachay-Cherkess Republic) with low mineralization (2.4 g/dm^3), taken at 3.0 mL/kg body weight 3 times daily 30 minutes before meals in warm form for 21 days.

In the main group (n = 43), in addition to the rehabilitation program of the second comparison group, patients received

transcutaneous electrical nerve stimulation (TENS) over the cervical sympathetic ganglia using the Simpatokor-01 device (Russia; medical device registration certificate FSR No. 2007/00757) according to the following protocol: with the patient in a seated position, special straps with embedded conductive elements (6 cathodes arranged around a central anode) were placed on the neck skin (pre-treated with a special gel) and secured to position the anodes over the projection of the cervical ganglia. Current was applied using sequential clockwise circuit closure between the anode of one strap and the 6 cathodes of the opposite strap. The stimulation parameters included a unipolar rectangular pulsed current with a pulse duration of 40 μs and frequency of 40 Hz. Current amplitude was individually adjusted for each patient (increased until mild tingling or vibration was perceived (2–3 V) in cases of vagotonia, and until ear lobe numbness was reported (4–5 V) in cases of sympathicotonia). Each 15-minute session consisted of 5 minutes of opposite strap circuit closure, 5 minutes of functional rest, and 5 minutes of stimulation with reversed current direction. The treatment course included 10 daily procedures.

Outcomes Registration

Clinical symptoms were assessed using the Edmonton Symptom Assessment System (ESAS) in all patients before and after rehabilitation [20]. This questionnaire evaluates the intensity of 9 common symptoms experienced by cancer patients: pain, tiredness, drowsiness, nausea, appetite, depression, anxiety, well-being, and bowel irregularities, where 0 indicates absence of the symptom and 10 represents maximal symptom severity.

Patients' quality of life (QoL) was also studied using the European Quality of Life Questionnaire EQ-5D [21]. The questionnaire comprises two sections: the first describes 5 QoL components (Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression), each rated as "no problems," "moderate problems," or "severe problems"; the second section assesses QoL using a visual analog scale (0 = worst health state, 100 = best health state).

Ethics Approval

This research was approved by the Ethics Committee of the Pyatigorsk Research Institute of Balneology, a branch of the North Caucasus Federal Scientific and Clinical Center of the Federal Medical-Biological Agency (Protocol No. 1 dated January 28, 2022).

Statistical Analysis

Statistical analysis was performed using STATISTICA 13.0 software. The reliability of differences was assessed by calculating mean values (M) and standard deviation (SD), presented as M ± SD. The strength of correlations was evaluated using Spearman's rank correlation coefficient (r). The level of $p < 0.05$ was considered statistically significant.

RESULTS

Participants

The study included 126 patients who underwent surgery for colorectal cancer at the age of 18 to 65 years. All patients were under oncologist follow-up.

Primary Results

Prior to rehabilitation, all patients who underwent surgery for colorectal cancer were assessed using the ESAS scale. The assessment revealed that the average severity of the most common symptoms was rated as moderate, scoring 5.1 ± 1.2 points (see Table 1). Patients most frequently reported increased tiredness, anxiety-depressive manifestations, and bowel disorders, with obstipation syndrome (less than 3 bowel movements per week) predominating in the majority of cases. Significant differences from population norms were observed [21, 22].

QoL assessment using the EQ-5D questionnaire showed that 73.9% of patients had moderate impairments, primarily in the domains of Mobility, Pain/Discomfort, and Anxiety/Depression, which aligns with Russian population norms [23].

The assessment of the effectiveness of outpatient rehabilitation using therapeutic physical factors demonstrated the feasibility of our developed rehabilitation program for patients after surgical intervention for colorectal cancer. The severity of ESAS symptoms in the main group decreased by an average of 2.6-fold compared to baseline values ($p < 0.01$), assessed as mild symptoms, most notably in the Pain, Depression, Nausea, and Bowel Dysfunction scales. Comparative analysis revealed intergroup differences across all scales in final outcomes, with similar data in the comparison group 1 where ESAS symptoms regressed by an average of 1.4-fold ($p < 0.05$). In comparison group 2, ESAS symptoms decreased by an average of 1.9-fold ($p < 0.05$), with a statistically significant advantage over final outcomes in the main group for the Depression, Anxiety, and Well-Being scales.

Similarly significant positive changes over time were observed in QoL parameters via the EQ-5D questionnaire: by the end of outpatient rehabilitation, 41.8% of patients in the main group reported no mobility issues, 44.2% no self-care difficulties, and 51.1% no limitations in daily activities. Pain syndrome regression was noted in 46.6% of cases, and anxiety-depressive syndrome in 53.5%, with intergroup differences identified compared to the comparison group 1. In comparison group 2, no issues was recorded in 32.5% of patients for mobility, 37.2% for self-care, 39.5% for usual activities, 32.5% for pain/discomfort, and 39.6% for anxiety/depression.

The most significant indicator demonstrating the advantage of our developed outpatient rehabilitation program for patients after surgical intervention for colorectal cancer

was the health status assessment using the visual analog scale: patients in the main group showed QoL recovery compared to baseline values by 1.7 times ($p < 0.01$) and in comparison group 2 by 1.5 times ($p < 0.05$), while comparison group 1 only demonstrated a trend toward improvement in this parameter. Monitoring of QoL parameter intensity using the EQ-5D questionnaire is presented in Table 2.

DISCUSSION

Direct criteria for evaluating the effectiveness of therapeutic interventions include assessment of patients' QoL, as it compares treatment programs at the group level [21–23]. It should be noted that our developed outpatient medical rehabilitation program for post-operative colorectal cancer patients incorporating physical therapy modalities demonstrated significant advantages in QoL parameters measured by ESAS and EQ-5D questionnaires. Specifically, the intake of mineral water included in the treatment programs of the main study group and comparison group 2 helped alleviate nausea and improve appetite through normalization of motor-secretory functions in the gastrointestinal tract. This therapeutic effect can be attributed to the beneficial impact on gastroentero-pancreatic system activity mediated by bicarbonates and sodium, which leads to neutralization of excess gastric hydrochloric acid secretion, restoration of metabolism and microcirculation processes, and improvement of gastroduodenal mucosal trophism [11, 15, 16]. The sanogenetic potential of mineral waters is demonstrated in the study by Kotenko et al. [23] during rehabilitation of patients with post-COVID syndrome.

The decision to include percutaneous electrical neurostimulation in the rehabilitation program for patients after surgical intervention for colorectal cancer was based on the well-established analgesic, anti-inflammatory, and spasmolytic therapeutic effects of the procedure [17,18,20]. As evidenced by multiple studies, this technique aims to provide symptomatic pain relief through the

Table 1. Monitoring of symptom severity by Edmonton ESAS (Score)

Parameters	Rehabilitation period	Group		
		Comparison 1 *n*=40	Comparison 2 *n*=43	Main *n*=43
		M±SD		
Pain	Before	3.8±1.5	3.9±1.7	3.8±1.4
	After	2.4±1.0**	1.8±1.2**	1.5±1.0**′
Fatigue	Before	5.3±1.6	5.5±1.4	5.4±1.7
	After	2.8±1.1**	2.2±1.2**	2.0±1.0**′
Somnolence	Before	4.2±1.3	4.4±1.6	4.4±1.5
	After	2.8±1.5**	2.0±1.2**	1.6±1.3**′
Nausea	Before	5.8±1.4	6.1±1.3	5.9±1.6
	After	3.7±1.5**	2.4±1.3**	2.2±1.6**′
Appetite	Before	4.9±1.4	4.8±1.6	4.8±1.2
	After	3.5±1.3**	2.4±1.7**	2.1±1.4**′
Depression	Before	5.1±1.6	5.4±1.5	5.3±1.3
	After	4.0±1.7*	3.6±1.4**	1.8±1.3**′
Anxiety	Before	5.3±1.5	5.3±1.3	5.4±1.6
	After	4.2±1.8*	3.1±1.4**	1.9±1.6**′
Dyspnea	Before	2.6±1.0	2.8±1.2	2.5±1.0
	After	1.3±0.8**	1.0±0.7**	0.8±0.5**′
Well-being	Before	5.3±1.5	5.6±1.3	5.5±1.6
	After	3.5±1.4**	3.4±1.5**	2.5±1.8**′
Stool disorders	Before	6.2±1.4	6.1±1.6	6.2±1.5
	After	4.9±1.7**	3.6±1.8**	3.2±1.4**′

Note. Validity of differences (p) before and after rehabilitation: * — <0.05; ** — <0.01; # — validity of differences with the control group by Pearson chi-square test.

Table 2. Monitoring of symptom quality of life by EQ-5D questionnaire

Parameters	Rehabilitation period	Group		
		Comparison 1 *n* = 40	Comparison 2 *n* = 43	Main *n* = 43
QoL domains, abs. (%)				
Mobility, score				
No problems	Before	2 (5)	2 (4.7)	2 (4.7)
Moderate problems		34 (85)	36 (83.7)	36 (83.7)
Severe problems		4 (10)	5 (11.6)	5 (11.6)
No problems	After	8 (20)	14 (32.5)	18 (41.8)
Moderate problems		29 (72.5)	27 (62.8)	23 (53.5)
Severe problems		3 (7.5)	2 (4.7)	2 (4.7)
Self-care, score				
No problems	Before	8 (20)	9 (20.9)	8 (18.6)
Moderate problems		26 (65)	27 (62.8)	27 (62.8)
Severe problems		6 (15)	7 (16.3)	8 (18.6)
No problems	After	14 (35)	16 (37.2)	19 (44.2)
Moderate problems		22 (55)	24 (55.9)	22 (51.1)
Severe problems		4 (10)	3 (6.9)	2 (4.7)
Ususal activities, score				
No problems	Before	6 (15)	7 (16.3)	7 (16.3)
Moderate problems		30 (75)	33 (76.8)	32 (74.4)
Severe problems		4 (10)	3 (6.9)	4 (9.3)
No problems	After	13 (32.5)	17 (39.5)	22 (51.1)
Moderate problems		25 (62.5)	25 (58.2)	21 (48.9)
Severe problems		2 (5)	1 (2.3)	-
Pain/discomfort				
No problems	Before	2 (5)	2 (4.7)	2 (4.7)
Moderate problems		30 (75)	32 (74.4)	32 (74.4)
Severe problems		8 (20)	9 (20.9)	9 (20.9)
No problems	After	7 (17.5)	14 (32.5)	20 (46.6)
Moderate problems		28 (70)	26 (60.6)	22 (51.1)
Severe problems		5 (12.5)	3 (6.9)	1 (2.3)
Anxiety/depression				
No problems	Before	2 (5)	2 (4.7)	2 (4.7)
Moderate problems		28 (75)	30 (69.7)	30 (69.7)
Severe problems		10 (25)	11 (25.6)	11 (25.6)
No problems	After	8 (20)	17 (39.6)	23 (53.5)
Moderate problems		27 (67.5)	22 (51.1)	19 (44.2)
Severe problems		5 (12.5)	4 (9.3)	1 (2.3)
Health state on VAS, M±SD				
QoL assessment	Before	51.3±8.2	50.7±8.5	49.2±9.1
	After	61.4±8.6*	76.2±9.8**	84.4±10.3**′

Note. Validity of differences (*p*) before and after rehabilitation * — <0.05; ** — <0.01; # — with the control group by Pearson chi-square test.

activation of sensory nerve fibers [11, 17, 20]. The effects of electrical neurostimulation are mediated by various neurotransmitters, including serotonin, whose receptors are present in multiple organs, including the intestines: on one hand, serotonin regulates negative emotions, leading to the regression of anxiety-depressive disorders; on the other hand, it participates in the modulation of intestinal motor function [24,25]. This dual mechanism explains the significant advantage in alleviating anxiety-depressive manifestations observed in the main patient group compared to both comparison groups.

The combined application of rational pharmacotherapy and therapeutic physical factors in patients with colorectal cancer during the outpatient phase significantly enhances rehabilitation outcomes. This is achieved through the synergistic action of the employed therapeutic factors and pharmacological agents, specifically pharmacological effects of medications; acid-regulating, reparative-regenerative, colon-modulating, and other effects of the Psyzh low-mineralized chloride-sulfate sodium-magnesium mineral water; and myorelaxant, spasmolytic, trophic, and vegetocorrective effects of percutaneous electrical neurostimulation.

CONCLUSION

The inclusion of therapeutic physical factors in outpatient medical rehabilitation programs for patients after colorectal cancer surgery leads to a significant improvement in quality of life.

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