EVALUATION OF THE EFFECTIVENESS AND SAFETY OF EXOSKELETON IN REHABILITATION PROGRAMS FOR PATIENTS WITH SPINAL CORD INJURY

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Objective. Evaluation of the effectiveness and safety of exoskeleton in rehabilitation programs for patients with spinal cord injury.
Material and Methods. A clinical study of the effectiveness of a rehabilitation program based on training in an exoskeleton was carried out on the basis of the Novosibirsk Research Institute of Traumatology and Orthopaedics n.a. Ya.L. Tsivyan in the period from 2017 to 2019. Rehabilitation trainings were conducted using Russian hardware and software complex. The study involved 80 people (57 men and 23 women) with spinal cord damage caused by the thoracic and lumbar spine injury. The duration of the injury ranged from 1 to 15 years, the average duration of the post-traumatic period was 73.4 ± 5.31 months.
Results. The rehabilitation program for each participant consisted of 2 sessions of 20 days each held in hospital setting and included training in ExoAtlet exoskeleton (at least 15 trainings, 30 minutes each during each hospital stay), specialized exercise therapy and physiotherapy procedures. The break between sessions was 1 month. The results of the SCIM III assessment showed a change in the level of active functioning towards improvement in half of the patients who underwent rehabilitation in the exoskeleton. Taking into account that patients with complete conduction disturbances (66.3%) and injury duration of more than three years (73.7 %) prevailed among the study participants, such results indicate the effectiveness of rehabilitation measures based on walking in exoskeleton, not only in recovery, but also in the late period of the injury, even with severe neurological deficit.
Conclusion. The obtained results allow recommending walking in an exoskeleton for inclusion in the rehabilitation programs for patients with paraplegia and paraparesis in the recovery and late periods of spinal cord injury.
Key Words: spinal cord injury, paraparesis, paraplegia, exoskeleton, rehabilitation, SCIM III scale.
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Injuries to the spine and spinal cord account for 10 to 17 % of all injuries to the musculoskeletal system. Spinal cord injury (SCI) is characterized by a severe course, high mortality rate, and a high incidence of primary disability [1, 2]. Spastic paraplegia of lower extremities, which develops in 20–30 % of SCI patients, has the highest disability risk. Rehabilitation of these individuals is a complex and cost-intensive process. No approaches to the individualized search for the optimal rehabilitation means and strategies have been identified yet, which makes the therapy less effective [3]. Rehabilitation using exoskeletons, which are innovative robotic devices containing an external frame for increasing human strength, opens up new possibilities for restoring lost motor functions and enhancing the preserved ones in patients with traumatic and non-traumatic spinal cord injuries. Although the first reports on the use of medical exoskeletons for rehabilitation of patients with impaired motor function of the lower extremities were published relatively recently, at the end of the 2000s, there are currently about 10 exoskeleton models manufactured in different countries that were proposed for rehabilitation purposes [4]. The first Russian exoskeleton "ExoAtlet" was registered as a robotic medical device in 2016.

All medical exoskeletons for mobility enhancement are hardware and software systems consisting of a mechanical structure that follows lower limb contours, electric motors, which are part of the structure, and a processor based on biological feedback controlling the exoskeleton during training. Domestic and foreign studies have shown that walking in the exoskeleton improves the patient's psycho-emotional state due to the possibility to stay in an upright position and increases his ability to self-care. It also activates and strengthens the musculoskeletal system due to continuous passive movements of all muscles and joints of the lower extremities. Restoration of walking function using a robot motivates the patient to actively participate in the rehabilitation process, although for a short time [5–7].

Despite the encouraging results obtained, the practical feasibility of using innovative robotic devices for rehabilitation of the disabled persons with spinal cord injury is still questioned. In addition to the high cost, as well as operational difficulties associated with the technical complexity of the design and software, which requires special skills, the widespread use of exoskeletons is hampered by the lack of consensus on the effectiveness of a rehabilitation program using a robotic device. Most authors have analyzed exoskeleton capabilities based on individual cases or clinical studies in a small group of participants [8]. Randomized clinical studies with a sufficiently large number of participants are required to resolve controversial issues and provide scientific evidence for the use of robotic exoskeleton training for comprehensive rehabilitation of SCI patients.

The aim of the study is to analyze the effectiveness and safety of using exoskeleton during recovery and late periods of spinal cord injury.

Material and Methods

A clinical study of the effectiveness of rehabilitation based on exoskeleton-assisted walking was carried out at Novosibirsk Research Institute of Traumatology and Orthopaedics n.a. Ya.L. Tsivyan in 2017–2019. The study was designed as a prospective, one-group, non-randomized, open-label, non-comparative, and baseline-controlled study. The Russian hardware and software platform ExoAtlet was used for rehabilitation. The inclusion criteria are the following: patient's age is in the range of 19–55 years; the weight does not exceed 100 kg; the height ranges from 160 to 190 cm; neurological damage is at the ⩽T1 vertebra level; impairment of sensory and motor conduction is classified as ASIA grade A–C; the patient can move independently in a wheelchair, perform self-care activities, use both upper extremities, and control muscle strength. The study included 80 patients (57 males and 23 females) with SCI in the thoracic and lumbar spine (Intent-to-treat (ITT) population of all the included patients). A total of 31.25 % of patients (25 individuals) had injury at the T1–T7 level, 40.00 % of cases (32 participants) received trauma at T8–T12, and 22.50 % of patients (18 individuals) were diagnosed with a L1–L5 level injury. There were five (6.25 %) patients with traumatic injury to the lower thoracic and upper lumbar vertebrae. Injury duration varied from one year to 15 years; the average duration of the post-traumatic period was 73.40 ± 5.31 months. A total of 21 (26.3 %) patients were in the recovery period (1–3 years after injury); 59 (73.7 %) individuals were in the late period (more than 3 years after injury). The clinical study protocol was approved by the local ethics committee. All patients involved in the study gave an informed consent. A total of 65 patients (Per Protocol (PP) population) completed their participation in the study; 15 participants dropped out for various reasons.

The rehabilitation program consisted of two 20-day courses conducted in stationary conditions for each participant. It included exercises using the ExoAtlet hardware-software platform (at least 15 30-min exercise sessions during each hospitalization), exercise therapy, physiotherapy procedures (electromyostimulation, as well as either magnetotherapy or laser therapy, if indicated), medical massage of the lower extremities and local spinal regions. The break between the courses was one month.

The effectiveness of rehabilitation measures was assessed before and after each course (visits 1–4), as well as one month after completion of the rehabilitation program (visit 5). The SCIM (Spinal Cord Independence Measure) III scale, which is recommended for objective assessment of functional recovery after spinal cord injury, was used as the main assessment tool [9]. The SCIM III scale allows one to score the quality of daily life and social functions. The total score presents the sum of intermediate points for the following sections: self-care (0 to 20 points), respiration and sphincter management (0 to 40 points), and mobility (0 to 40 points); it reaches 100 points in the absence of neurological deficit [10].

The ASIA/ISNCSCI scale (2015), which is the international standard for neurological and functional classification of spinal cord injuries, was used to determine the severity of neurological deficits [11].

In order to assess the safety throughout the entire period of the patient's participation in the clinical study, vital signs (blood pressure, heart and respiratory rate), patients' complaints and physical condition, and all adverse events (i.e. any unfavorable change from a medical standpoint) were monitored. Data on adverse events were recorded in the primary documentation and individual registration cards with subsequent analysis of the presence or absence of causal relationships with the rehabilitation method under study.

The obtained data were processed using the IBM SPSS Statistics software version 25.0 by calculating descriptive statistics and performing an intra-group comparison of scale parameters. Descriptive statistics are presented as mean (M) and standard deviation (SD). The statistical significance of the differences between the scale parameters was assessed using the non-parametric Wilcoxon signed-rank test and the non-parametric Friedman test. The alpha level for accepting or rejecting the null hypothesis was considered as 0.05. The corrected alpha level for the Friedman test, with taking into account the Bonferroni correction for four independent tests, was considered as 0.0125.

Results

Assessment of neurological status using the ASIA scale during visit 1 revealed that the majority (66.3 %) of the participants initially had complete neurological impairment, which caused the loss of motor function of the lower extremities, as well as pain and tactile sensitivity below the neurological level. A total of 13.7 % of the patients were unable to move their legs, while having a preserved, although significantly reduced, sensitivity below the injury level (Table 1).

The motor function of the lower extremities was partially preserved in

20.0 % of the patients. However, these individuals, as well as ASIA grade A and B patients, used a wheelchair for independent mobility due to severe neurological deficit, which significantly decreased strength of the key muscles below the injury level.

A total of 15 patients dropped out between visits 2 and 4 during the clinical study period. Patient disposition based on the study visits, including individuals who prematurely discontinued participation with specification of the main reasons for dropping out, is presented in the Fig.

The adverse events were stratified as either mild (n = 5 (6.25 %) of the total number of study participants) or moderate (n = 6 (7.50 %) of the total number of participants). Analysis of the degree of spinal cord injury in patients with adverse events using the ASIA impairment scale showed that nine out of 11 patients had the highest injury grade (ASIA grade A).

Adverse events of mild severity (five cases, which occurred during walking in the exoskeleton) included manifestations of edema and pain in either ankle (three cases) or knee (two cases) joints. Radiological examination revealed stage ⩾II osteoarthritis in all the cases, while the adverse events were insignificant and neither led to the patients' refusal to participate in the clinical study nor increased the duration of hospitalization/rehabilitation.

Moderate adverse events were observed in six patients: ankle (five cases) and knee (one case) joint fractures occurred during exoskeleton use, which led to the cancellation of rehabilitation. Fractures in SCI patients were regarded as adverse health threatening events requiring prolongation of hospitalization. Monitoring of the patients' condition revealed fracture consolidation in all patients and no deterioration in general health and neurological status, as observed in the control images 8–10 weeks after fracture.

Assessment using the ASIA scale during visit 5 did not reveal any changes in the patients' neurological status during rehabilitation (Table 1). The distribution of patients between grades A, B, and C in the PP population remained the same as for the ITT population before the beginning of rehabilitation. Quantitative assessment of motor and sensory functions also revealed neither positive nor negative dynamics after two courses of rehabilitation.

In order to assess the impact of rehabilitation measures on the patients' functional status, the dynamics of the total SCIM III score in the PP population from visit 1 to visit 5 was statistically analyzed (Table 2).

The mean total SCIM III score increased by 3.20 ± 0.50 points relative to the initial value and equaled 69.70 ± 9.45 points (M ± SD) by visit 5. Statistical analysis using the non-parametric paired Wilcoxon test performed to establish the significance of differences in the parameter between visits 1 and 5 showed that the mean values differed significantly (Z = -2.250; p = 0.023). The least significant change in the total score was observed in ASIA grade A patients: the increase was only 0.900 ± 0.218 points in this group. The greatest increase in the SCIM (by 4.60 ± 0.22 points relative to the period before the start of rehabilitation) was noted in the grade C group. However, this increase was not statistically significant, which may be due to the small number of patients in the group (16 individuals). Positive dynamics in the total score was found in both the total group and ASIA subgroups A, B, and C at visit 4. This trend continued for a month after completion of rehabilitation. Thus, the total SCIM III score reached its maximum values by visit 5.

The proportion of participants whose total SCIM III score increased by ⩾ 1 point after rehabilitation was 50.8 % (33 individuals). Moreover, seven patients had an increase of 10 to 40 points. The total score remained the same in 18 (27.7 %) cases; negative dynamics in the range from 1 to 9 points was observed in 14 (21.5 %) individuals. The proportion of patients with positive dynamics during rehabilitation was comparable between ASIA subgroups A, B, and C (50.0, 55.6, and 50.0 %, respectively). The vast majority of patients with negative dynamics were classified as grade A (12 out of 14 patients).

In order to answer the question of what functional area was influenced by rehabilitation using the exoskeleton, we analyzed the nature of changes in the intermediate score for sections "self-care", "respiration and sphincter management", and "mobility" (Table 3).

Before the start of rehabilitation, the most restricted function among the patients was self-care, which includes daily activities such as eating, dressing, and personal hygiene. On the one hand, a relatively insignificant restriction in self-care can be explained by the fact that the level of neurological damage is ⩽ T1. On the other hand, it is because the patients have to adapt to the need to change their lifestyle in the late period of SCI [12, 13]. Respiration and sphincter management were reduced by 23 % due to the impaired control of urination and defecation. Respiration was not affected: the patients were adapted to use the toilet independently with the help of assistive devices. The most restricted function was mobility. The mean score for this section was reduced by 54 % during visit 1. This was expected because all study participants moved in a wheelchair, could neither stand nor walk, and, even when having the skills to use a wheelchair, they experienced difficulties when moving outdoors, and could not go down and up the stairs.

A tendency to an increase in the functioning level was noted for all three sections during rehabilitation. However, comparison of the mean score before and one month after the end of rehabilitation demonstrated a significant increase only for section "respiration and sphincter management" (p_{1-5} = 0.037; Table 3). An analysis of personal SCIM III questionnaires showed that positive dynamics for this section is associated with the ability to defecate independently at least once every three days in (6.2 %) patients and improved urination control in three (4.6 %) cases. An intragroup comparison (visits 1–5) of the scores for all SCIM sections using the Friedman method, which allows to simultaneously compare the values of the studied vari-

Table 1
Neurological impairment degree according to the ASIA scale in patients with spinal cord injury before/after rehabilitation (n = 80/65)

Impairment degree	Patients, n (%)	Motor function, points*	Sensitivity, points*	
			pain	tactile
A – complete: no sensory or motor function is preserved in segments S4–S5	53/44 (66.3/67.8)	51.00 ± 0.22/ 52.30 ± 0.29	69.10 ± 0.22/ 69.80 ± 0.31	69.10 ± 0.22/ 69.40 ± 0.28
B – incomplete: only motor function (no sensitivity) is preserved below the neurological level (including S4–S5)	11/9 (13.7/13.8)	52.60 ± 0.37/ 54.10 ± 0.61	81.70 ± 0.74/ 82.00 ± 0.66	81.70 ± 0.74/ 82.00 ± 0.66
C – incomplete: motor function is preserved below the neurological level, the strength of the majority of key muscles below the neurological level is graded < 3 points	16/12 (20.0/18.5)	71.80 ± 0.69/ 72.70 ± 0.74	93.60 ± 0.41/ 93.50 ± 0.52	93.60 ± 0.41/ 93.50 ± 0.52
Total	80/65 (100.0/100.0)	52.70 ± 0.59/ 53.50 ± 0.42	77.30 ± 0.36/ 77.80 ± 0.47	77.30 ± 0.36/ 77.70 ± 0.49

The numerator presents scores before the beginning of rehabilitation (visit 1), the denominator contains scores after the end of rehabilitation (visit 5);
*in the absence of neurological impairment, the maximum score for the motor and sensory functions on both sides is 100 and 112, respectively.

able for all five visits, taking into account the Bonferroni correction for multiple testing, confirmed significant differences between the visits for section "respiration and sphincter management"(Q = 14.459; p = 0.006) and revealed statistically significant positive changes in the mean score for mobility (Q = 13.473; p = 0.009) after rehabilitation. No significant differences were noted for self-care (Q = 9.223; p = 0.056). The absence of significant changes in the intermediate score for this section can be explained by the fact that the functioning level of the patients remained quite satisfactory before the beginning of rehabilitation, and the mean score was only 11.0 % lower than the maximum possible value.

Discussion

The results of statistical processing of the clinical version of the SCIM III scale indicate an improvement in the functioning level in half of the patients receiving exoskeleton-based rehabilitation. The specialized SCIM III questionnaire is currently used in international practice as one of the basic tools for assessing rehabilitation outcomes in spinal cord injury. The criterion for the adequacy and effectiveness of the implemented

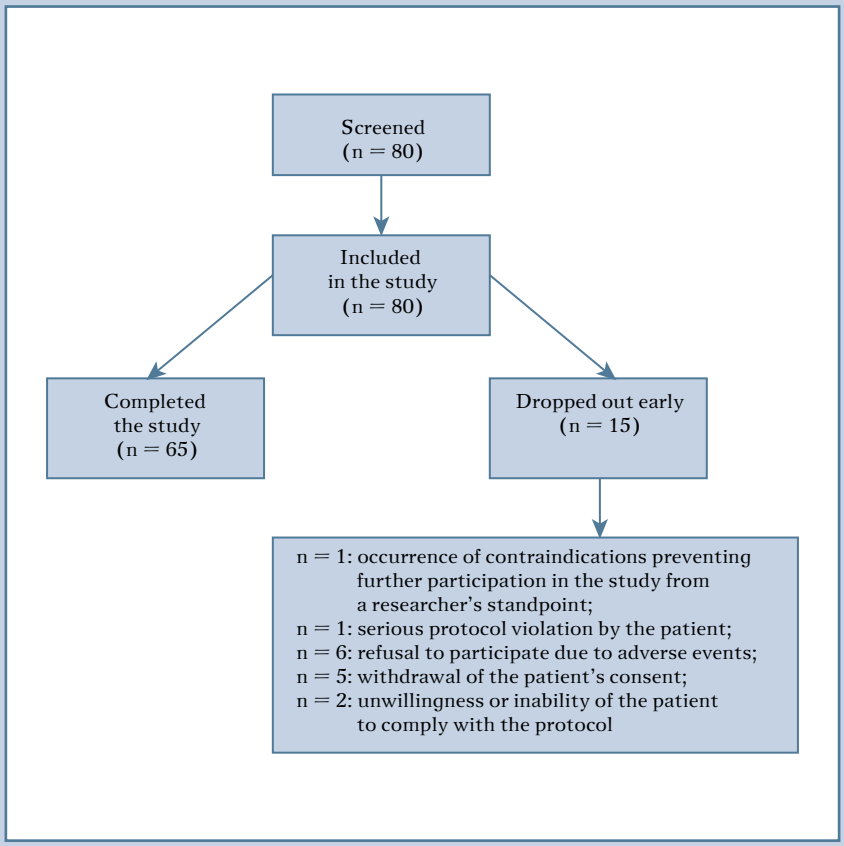

Fig.
Disposition of patients included in the study

Table 2
Dynamics of the mean total SCIM III score after comprehensive exoskeleton-assisted rehabilitation (n = 65)

ASIA grade	Mean SCIM score (M±SD)				
	visit 1	visit 2	visit 3	visit 4	visit 5
A (n = 44)	65.50 ± 7.51	65.20 ± 7.42	64.90 ± 7.34	66.00 ± 6.75	66.40 ± 6.76
B (n = 9)	66.80 ± 11.48	67.20 ± 10.16	68.10 ± 15.43	68.00 ± 15.41	69.10 ± 15.27
C (n = 12)	72.20 ± 12.13	72.20 ± 12.12	74.50 ± 11.56	76.30 ± 9.90	76.80 ± 8.03
The whole group (n = 65)	66.50 ± 10.22	67.20 ± 9.74	67.50 ± 10.44	68.30 ± 10.02	69.70 ± 9.45* $p_{1-5} = 0.023$

*statistical significance of the differences compared to baseline values.

rehabilitation program is an increase in the total score during rehabilitation [14, 15]. In our study, the mean total score increased by 3.20 ± 0.50 points by the final visit (visit 5). It is worth noting that some authors consider a 1-point increase as an indicator of treatment effectiveness [16].

Taking into account the fact that patients with complete conduction disturbances (66.3 %) and more than 3-year trauma duration (73.7 %) prevailed among the participants, these results indicate effectiveness of the rehabilitation program based on walking in the exoskeleton not only during the recovery period but also in the late period of injury, even in severe neurological deficits. The absence of the effect of exoskeleton-based rehabilitation program on the degree of neurological deficit was expected, since the overwhelming majority of the study participants were in the late period, when neurological condition is stable. The main rehabilitation goal during this period is to increase the patient's mobility and ability to self-care, as well as to prevent and correct internal organ disorders and the patient's psycho-emotional status [3, 17]. The rehabilitation program based on exoskeleton-assisted gait training meets these goals, which is evidenced by a significant increase in the mean score for sections "mobility" and "respiration and sphincter management". Of particular interest is the positive dynamics in pelvic organ functions, since improvement in the control of urination and defecation remains one of the most difficult tasks in managing SCI patients [18, 19]. The obtained results are consistent with the data of other authors reporting improved control of defecation after exoskeleton-assisted walking. Mechanisms for improving the function of anal sphincters may be explained by a tendency to normalize the tone of the pelvic diaphragm muscles, the diaphragm itself, as well as by increased intra-abdominal pressure during systematic standing in upright position and walking in the exoskeleton [20, 21]. Baunsgaard et al. [16] performed a multicenter clinical study using the "Ekso GT" exoskeleton and also noted an improvement in stool incontinence. However, the authors did not reveal any changes in bladder function, which was impaired in all patients. It should be noted that mean intermediate scores for each of the sections and the total score did not change after the first course of rehabilitation; improvement was observed only during the second course of the recovery program. Other authors recommend long (⩾8-week) rehabilitation period with at least 25–30 sessions [22, 23]. Each participant in our study received 30–36 sessions in the exoskeleton for the period of 2.5 months, which included two stationary periods with a one-month break. During the first course, the patients were able to start walking independently in the exoskeleton with a cane and with the help of an assistant only after the adaptation period, which included at least 8–10 sessions of standing in the device with crutch support and bar walking. The literature provides data that certain effects can be achieved after 15 rehabilitation sessions in the exoskeleton. Neurological impairment degree in these patients is usually incomplete, which corresponds to ASIA grades B and C [24].

During the study, six patients developed complications in the form of lower limb fractures. This complication is a serious adverse event. However, it is expected when walking in the exoskeleton [6, 25]. Cases with a severe degree of spinal cord injury predominated among patients with fractures: five individuals were classified as ASIA grade A. These patients are known to naturally develop osteoporosis and also have an increased risk of fractures even in the absence of physical activity [26].

Conclusion

The functional status of patients with severe neurological impairment (ASIA grades A and B in 80 % of the study participants) improved after exoskeleton-assisted rehabilitation in the recovery and late periods. The effectiveness of walking in the exoskeleton was confirmed by statistical data analysis using the clinical version of the SCIM III scale. According to SCIM III-based evaluation results, the total score increased by 1.80 ± 0.76 points by the end of rehabilitation and by 3.20 ± 0.50 points one month after the completion of the recovery program. Analysis of the dynamics of the total and intermediate SCIM III scores during rehabilitation demonstrated that the effectiveness of recovery based on walking in the exoskeleton depends on the recovery period duration, which should include at least 30 sessions.

The obtained results allow recommending exoskeleton-assisted walking

Table 3

Dynamics of the mean intermediate score for each SCIM III section after comprehensive exoskeleton-assisted rehabilitation (n = 65)

Section	Maximum score	SCIM section score (M ± SD)				
		visit 1	visit 2	visit 3	visit 4	visit 5
Self-care	20	17.80 ± 2.23	17.50 ± 2.43 $p_{1-2} = 0.350$; $p_{2-5} = 0.030$*	17.90 ± 2.41 $p_{1-3} = 0.128$; $p_{3-5} = 0.428$	18.10 ± 1.79 $p_{1-4} = 0.140$; $p_{4-5} = 0.713$	18.20 ± 1.70 $p_{1-5} = 0.101$
Respiration and sphincter management	40	31.00 ± 6.14	31.30 ± 5.43 $p_{1-2} = 0.386$ $p_{2-5} = 0.061$	31.10 ± 5.86 $p_{1-3} = 0.386$ $p_{3-5} = 0.023$*	31.50 ± 5.12 $p_{1-4} = 0.088$ $p_{4-5} = 0.113$	31.90 ± 4.43 $p_{1-5} = 0.037$*
Mobility	40	18.40 ± 4.36	18.30 ± 5.06 $p_{1-2} = 0.433$ $p_{2-5} = 0.156$	18.60 ± 4.77 $p_{1-3} = 0.811$ $p_{3-5} = 0.089$	19.30 ± 4.64 $p_{1-4} = 0.081$ $p_{4-5} = 0.882$	19.10 ± 4.61 $p_{1-5} = 0.385$

*the level of statistical significance of the differences between the compared visits (the visit No is in lower case).

for rehabilitation in patients with paraplegia and paraparesis during the recovery and late periods of spinal cord injury.

A decrease in the total score was noted in 21 % of the study participants. A total of 86 % of the patients with negative dynamics were classified as ASIA grade A. Adverse events associated with the studied rehabilitation method were also observed mainly in grade A patients. Apparently, further clinical studies are required in order to develop an effective and safe technology for using a robotic exoskeleton in patients with severe spinal cord injury due to trauma.

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The authors declare that there is no conflict of interests.

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