ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

Comparison of the Patients with Complete and Incomplete Spinal Cord Injury Administered Robotic-Assisted Gait Training Treatment

Robot Yardımlı Yürüme Eğitimi Tedavisi Uygulanan Komplet ve İnkomplet Spinal Kord Yaralanmalı Hastaların Karşılaştırılması

Çiğdem ÇINARᵃ, Kadriye ÖNEŞᵃ, Mustafa Aziz YILDIRIMᵃ, Gökşen GÖKŞENOĞLUᵃ

ᵃİstanbul Physical Medicine and Rehabilitation Training and Research Hospital, İstanbul, TURKEY

ABSTRACT Objective: The aim of the study was to compare the efficiency of robotic-assisted gait training applied during the subacute period for the patients with complete and incomplete spinal cord injury. **Material and Methods:** Thirty-four patients were included in the study. The patients were divided into two groups. The first group consisted of the patients with complete spinal cord injury and the second group comprised patients with incomplete spinal cord injury. Both groups were provided 10 robotic treatment training sessions in addition to conventional treatment. Walking Index Spinal Cord Injury II (WISCI II) was used to evaluate functional ambulation. The functional status of the patients was evaluated using Functional Independence Measurement (FIM). The quality of life was evaluated using Short Form 36 (SF-36). **Results:** Significant improvement was observed in both groups according to WISCI II results and FIM scores (p<0.001). For both groups, the baseline scores and after-treatment scores did not exhibit a significant difference in all subscales of SF-36 (p>0.05). While only after-treatment physical activity scores demonstrated a significant increase compared to the baseline scores in Group 1 and 2 (p<0.05), the after-treatment scores did not show a significant change compared to the baseline scores in the other measurements of SF-36 subscales (p>0.05). **Conclusion:** Robotic-assisted gait training treatment has effects on functional status, gait and daily living activities for the patients with complete and incomplete spinal cord injury. However, we were unable to identify any difference in terms of activity between complete and incomplete spinal cord injury in the subacute period.

Keywords: Spinal cord injury; gait; robotic rehabiliation; lokomat

ÖZET Amaç: Çalışmanın amacı, subakut dönemde uygulanan robot yardımlı yürüyüş eğitiminin, komplet ve inkomplet spinal kord yaralanmalı hastalarda etkinliğini karşılaştırmaktı. **Gereç ve Yöntemler:** Otuz dört hasta çalışmaya alındı. Birinci grup komplet, ikinci grup ise inkomplet spinal kord yaralanmalı hastalardan oluşmaktaydı. Her iki gruba da 10 seans robot yardımlı yürüme eğitimi ve konvansiyonel tedavi uygulandı. Fonksiyonel ambulasyonu değerlendirmek için Spinal Kord Yaralanması için Yürüyüş İndeksi (SKYYİ II) kullanıldı. Hastaların fonksiyonel düzeyini belirlemek için Fonksiyonel Bağımsızlık Ölçütü (FBÖ) kullanıldı. Yaşam kalitesi Kısa Form 36 (KF-36) ile değerlendirildi. **Bulgular:** Her iki grupta da SKYYİ II, FBÖ skorlarına göre anlamlı gelişim gözlendi (p<0.001). Her iki grup için başlangıç skoru ve tedavi sonrası skor KF-36'nın tüm alt birimlerinde anlamlı bir farklılık göstermedi (p>0.05). Sadece tedaviden sonra fiziksel aktivite skoru, Grup 1 ve 2'deki başlangıç seviyesine göre anlamlı bir artışa sahipken (p<0.05), tedaviden sonra puanların diğer skorlardaki başlangıç puanlarına göre anlamlı bir değişiklik göstermedi (p>0.05). **Sonuç:** Robot yardımlı yürüme eğitimi tedavisinin komplet ve inkomplet spinal kord yaralanmalı hastaların fonksiyonel durumları, yürüme ve günlük yaşam aktiviteleri üzerinde etkileri vardır. Ancak, subakut dönemdeki komplet ve inkomplet spinal kord yaralanmalı hastalar arasında aktivite açısından herhangi bir fark bulunamadı.

Anahtar Kelimeler: Omurilik yaralanması; yürüyüş; robotik rehabilitasyon; lokomat

Critical factors for determining a patient's prognosis after spinal cord injury (SCI) include the location of the lesion, whether there is complete or incomplete spinal cord injury as diagnosed by physical examination and American Spinal Injury Association Impairment Scale (AIS) scores.[1]

The sensory and motor examinations constitute the two most important portions of a neurological examination for a patient with spinal cord injury. After these two examinations are performed, the specialist can determine the patient's neurological injury level, sensory and motor levels, sensory and motor index scores, and whether the injury is complete or incomplete.

After sensory and motor examinations are performed and the neurological level is determined, the patients are examined according to the criteria of five classes: AIS A, B, C, D and E. If no sensory or motor functions are preserved at sacral levels 4 and 5, the patient is classified as AIS A. If at S4-5 level, one of the senses of light touch, pin-prick, or deep anal pressure is preserved, the patient is classified as AIS B-C-D-E with or without motor protection at three levels below the motor level. American Spinal Injury Association Impairment Scale (AIS) is used to assess motor and sensory levels of the injury. The AIS grade A indicates complete spinal cord injury, and AIS grades B, C and D indicate incomplete SCI.[2]

The most rapid motor recovery typically occurs within the first 2 months after the injury and functional recovery continues for up to 6-12 months. More than 50% of the patients with spinal cord injury (SCI) have incomplete injuries, and many of these patients are able to regain ambulatory functions. Patients with complete injuries have less potential for functional recovery.[3,4] Recurrent and task-specific functional training was evaluated as useful in self-recovery and sensory integration of the spinal cord after injury.[5] This concept, called neuroplasty, covers functional, structural, anatomical and neurophysiological processes. This process includes collateral germination and new synaptic regulations at the side of an uninjured tissue and damaged axon, and it is not based on whether damage is complete or incomplete.[6] Frequent, recurring, challenging, intense, multisensorial and task-specific rehabilitation approaches are needed for central nervous system plasticity. Gait is a good exercise for recurring motion. The best example for recurring motion in the lower extremities is gait exercise in which the appropriate joint range of motion exercises is performed via repetitive angled motions at the lower extremities, and nerve regeneration can be facilitated.[7] This locomotor training that incorporates high-level repetitions of task-oriented practice using body-weight support treadmill training (BWSTT) was introduced as a promising treatment concept for patients with SCI. Body-weight Support Treadmill Training (BWSTT) enables early initiation of gait training, integration of weight-bearing activities, stepping and balance by using a task-specific approach and symmetrical gait pattern.[8] Introduced in the late 1990s, robotic-assisted gait training maintains a type of physiological walking and enables frequent repetition of the task-specific practice by boosting the patient's ability to increase the intensity and total time of the training.[9-11] These systems contribute to motor learning by generating only simple and repetitive stereotyped motion models as well as providing visual and aural feedback for the patients.[12]

In addition to the studies using robotic-assisted gait training that are frequently conducted in patients with incomplete SCI, studies are available with the patients with complete SCI in the literature.

The aim of this study was to evaluate the effects of robot-assisted gait training in the patients with SCI and compare the effectiveness of robot-assisted training between patients with complete and incomplete SCI. To date and to the best of our knowledge, this study is the first documentation of this nature in the literature.

MATERIAL AND METHODS

The study was conducted with 34 patients who met the inclusion criteria in the neurological rehabilitation clinic of our hospital between February 2018 and October 2018. Patients with AIS A according to the AIS criteria were determined as complete; patients with AIS B, AIS C and AIS D were evaluated as incomplete. The patients were divided into two groups as complete and incomplete patients using a block randomisation method. The demographic and clinical characteristics (SCI aetiology, SCI level) of the groups were homogeneous. In both groups, robotic treatment training was given for a total of 10 sessions for 5 weeks, twice a week and conventional treatment (range of motion, stretching, strengthening and walking training) was provided 5 days a week (twice daily).

INCLUSION CRITERIA

■ Complete and incomplete patients with SCI per American Spinal Injury Association Impairment Scale (AIS) levels A-B-C-D

■ Patients with SCI, aged 18-65 years

■ Patients with SCI, the next 3 to 6 months after spinal cord injury

■ Patients with SCI and can walk independently before the injury

EXCLUSION CRITERIA

■ Patients who had previously received robotic therapy

■ Presence of severe spasticity, rigidity, contracture and fracture at the lower extremities

■ Presence of severe osteoporosis

■ Pressure ulcers at the lower extremities and pelvic zone

■ Other neurological disorders to affect gait

■ Uncontrolled cardiac diseases, pregnancy, severe cognitive and communicative disorder

■ Patients weighing over 150 kg

ROBOTIC-ASSISTED GAIT TRAINING SYSTEM

Lokomat (Hocoma AG, Zurich, Switzerland) system has a treadmill that allows for robotic gait via motors at the hip and knees within the exoskeleton and is integrated to the system. It has a real-time strength control computer controlling four motors in Robotic Gait Orthosis and a Feedback Monitor to motivate and engage the patient. It has ergonomically structured holding bars with adjustable height and front width that the patients can use during treatment. The system has a unique feature in that the patient's weight is at the desired level and is dynamically adjusted at every gait phase for this individual patient. The speed of robotic gait orthosis can be adjusted from 0.1 km/h to 3.2 km/h, and it can be used for the patients weighing up to 150 kg (Figure 1).

EVALUATION PARAMETERS

All of the patients were evaluated at the beginning and at the end of the treatment. American Spinal Injury Association Impairment Scale (AIS) was used to

FIGURE 1: Lokomat, a robot-assisted gait training system.

determine the patient's impairment level.[13] Walking Index Spinal Cord Injury II (WISCI II) was used to evaluate the patient's functional ambulation. This index which was developed to assess walking capacity after SCI, can measure very well the necessary devices and physical aid and WISCI I is a functional capacity scale designed to measure improvements in ambulation in people with SCI by assessing the amount of physical assistance, support, or equipment needed to walk 10 m.

Participants are systematically advancing to maximum walking capacities through a range of verified levels of capacity, including devices and personal assistance.

Walking Index Spinal Cord Injury II (WISCI II) is a scale that evaluates ambulation levels between 0 and 20 points. Based on the individual's own ambulatory conditions, patients are ranked from 0 (no ambulation) to 20 (independently ambulated).[14] The functional independence levels of the patient were evaluated using Functional Independence Measure (FIM) scores. FIM contains 13 motor and five social-cognitive topics. Topics include self-care, sphincter-care, transfer, locomotion, communication, social relation and cognitive activity. Scales with seven levels are used for scoring total independence. Level 1 means fully dependent, whereas level 7 means fully independent. Other levels are as follows: level 6, modified independent; level 5, under supervision; level 4, minimal assistance and consumption of >75% of the effort; level 3, medium assistance and consumption of 50-75% of the effort; and level 2, maximal assistance or consumption of 25-49% of the

effort.[15] Short Form 36 (SF-36) was completed to evaluate the participants' quality of life. The scale comprises 36 items, which cover eight different dimensions related to health, physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, mental health. The scores of items are coded and added together for each dimension. They are converted into a scale with points ranging from zero (the worst health) to 100 (best condition).[16] All of the patients were evaluated by a blinded researcher (Ç.Ç.) at the commencement and at the end of the treatment (single-blinded study).

Approval for the study was obtained from the Bakırköy Sadi Konuk Training and Research Hospital's Ethics Committee, and the study group was informed about the purpose and the content of the study. All of the patients provided their written informed consent. The study was conducted in accordance with the principles of the Declaration of Helsinki.

STATISTICAL ANALYSIS

The mean ± standard deviation, median (minimum, maximum), frequency and rate values were used for definitive statistics of the data. The distribution of variables was measured using the Kolmogorov-Smirnov test. The Mann-Whitney U test was used for analysis of quantitative independent data. The Wilcoxon test was used for analysing the dependent quantitative data. The chi-squared test was used for analysing the qualitative data. Statistical Package for Social Sciences (SPSS) 22.0 was used to perform statistical analyses.

RESULTS

The patients were divided into two groups. The level of the spinal cord lesion varied from C6 to L1. Demographics, aetiology, AIS scale and motor level zones are shown in Table 1. Age, gender, aetiology traumatic and nontraumatic ratios (p=0.115, p=0.818, p=0.928, respectively) did not vary between groups.

In terms of baseline WISCI II scores, after-treatment WISCI II scores, the complete and incomplete within group did not demonstrate a significant difference (p=0.287). For complete injury patients, the after-treatment WISCI II scores showed a significant increase compared to the scores at the time of admission (p=0.008). In incomplete patients, after-treatment WISCI II scores demonstrated a significant increase compared to the baseline scores (p=0.002), WISCI II score improvement did not exhibit a significant difference between the incomplete and complete injury patients in Group 1 (p=0.364) (Table 2).

TABLE 1: Demographic and clinical characteristics of the patients.		
	Complete (n=17)	Incomplete (n=17)
	Median (min-max)	Median (min-max)	p
Age (years)	31.5 (17-67)	34.0 (17-77)	0.115^m
Duration of disease (months)	3.18 (3-6)	3.89 (3-6)	0.169
	n (%)	n (%)	
Gender			
Female	6 (38.2%)	5 (35.5%)	0.818$^{X^2}$
Male	11 (61.8%)	12 (64.5%)	
Aetiology			
Traumatic	13 (76.5%)	14 (77.4%)	0.928$^{X^2}$
Nontraumatic	4 (23.5%)	3 (22.6%)	
Motor level			
C	3 (17.6%)	3 (17.6%)	0.749$^{X^2}$
L	4 (23.5%)	3 (17.6%)	
T	10 (58.9%)	11 (64.5%)	

^{m}Mann-Whitney U test; X^2: Chi-squared test.
C: Cervical; L: Lumbar; T: Thoracic.

TABLE 2: Comparison of groups in terms of disability level (FIM) and functional ambulation (WISCI II).			
	Complete	**Incomplete**	
	Median (min-max)	**Median (min-max)**	**p**
FIM			
Baseline	64.0 (47-120)	78 (22-110)	0.117[m]
After	80.0 (65-120)	88.0 (22-116)	0.051[m]
Baseline-after change	4.0 (0-49)	11.0 (0-40)	0.351[m]
Intra-group change p	**0.000**[w]	**0.001**[w]	
WISCI II			
Baseline	5.0 (0-22)	8.0 (0-22)	0.287[m]
After	7.0 (4-23)	9.0 (0-23)	0.058[m]
Baseline-after change	1.0 (0-13)	2.0 (0-5)	0.364[m]
Intra-group change p	**0.008**[w]	**0.002**[w]	

[m]Mann-Whitney U test; [w]Wilcoxon test.

FIM: Functional Independence Measure; WISCI II: Walking Index Spinal Cord Injury II.

Complete and incomplete injury patients in Group 1 did not demonstrate a significant (p=0.117) difference in terms of baseline FIM scores, after-treatment FIM values. For complete injury patients, after-treatment FIM scores demonstrated a significant increase compared to the scores at the time of admission (p<0.001). In incomplete injury patients, after-treatment FIM scores exhibited a significant increase compared to the baseline scores (p=0.001). The change in FIM scores did not indicate a significant difference between the incomplete and complete groups in Group 1 (p=0.351) (Table 2).

For both groups, baseline scores and after-treatment scores did not demonstrate a significant difference in nearly all subscales of SF-36 (p>0.05). Only the after-treatment physical activity scores showed a significant increase compared to the baseline scores in Group 1 and 2 (p=0.044, p=0.046), and after-treatment scores did not indicate a significant change compared to the baseline scores in the other scores (p>0.05). Improvement of SF-36 scores did not exhibit a significant difference between the groups (p>0.05) (Table 3).

DISCUSSION

In our study, robotic treatment was observed to have effects on functional status, gait and daily life activities for complete and incomplete patients. We were unable to identify any difference in terms of activity between the two groups. Robotic gait training and conventional treatment were provided to the study patients. In the conventional treatment, joint range of motion, stretching, strengthening and balance exercises were practised.

There is a limited number of randomised, controlled studies evaluating the impact of robotic treatment on gait, functional independence and quality of life. Therefore, not only the impacts of robotic treatment on gait, function and quality of life are still unclear but also there are insufficient thought and guidance with respect to when to commence treatment and what is the optimal treatment duration. In our study, the average time after injury was 3 months. Incomplete injury patients with SCI have regional sensorial and motor function. Within 1 year from the onset of injury, 80% of the patients reach up to their highest functional level. The best neurological recovery was observed within 6 months from the time of injury, while neurological recovery in months 12-15 starts to plateau.[17] Recently conducted studies have reported that more than 50% of individuals with SCI have motor incomplete lesion. The majority of the subjects with incomplete SCI who initially had motor function can partially recover their ambulatory function. It has been observed that patients with complete injury and with partially protected zones recover to the same extent as the patients with complete injury. The basis for the

TABLE 3: Comparison of groups in terms of Short Form-36 (SF-36).		
	Complete	**Incomplete**	
	Median (min-max)	**Median (min-max)**	**p**
Physical Functioning			
Baseline	0.0 (0-100)	0.0 (0-100)	0.894[m]
After	10.0 (0-100)	10.0 (0-100)	0.901[m]
Baseline-after change	0.0 (0-30)	0.0 (0-50)	0.908[m]
Intra-group change p	**0.044[w]**	**0.046[w]**	
Role-Physical			
Baseline	100.0 (0-100)	100.0 (0-100)	0.815[m]
After	100.0 (0-100)	100.0 (0-100)	0.518[m]
Baseline-after change	0.0 (0-40)	0.0 (0-30)	0.653[m]
Intra-group change p	0.058[w]	0.061[w]	
Bodily Pain			
Baseline	74.0 (22-100)	74.0 (22-100)	0.223[m]
After	77.0 (22-100)	77.0 (22-100)	0.238[m]
Baseline-after change	0.0 (0-30)	0.0 (0-35)	0.836[m]
Intra-group change p	0.052[w]	0.058[w]	
General Health			
Baseline	52.0 (20-82)	52.0 (20-82)	0.795[m]
After	52.0 (35-90)	56.0 (20-80)	0.617[m]
Baseline-after change	0.0 (0-20)	0.0 (0-26)	0.053[m]
Intra-group change p	0.057[w]	0.317[w]	
Vitality			
Baseline	50.0 (20-80)	45.0 (20-80)	0.635[m]
After	50.0 (20-80)	50.0 (20-80)	0.834[m]
Baseline-after change	0.0 (0-30)	0.0 (0-30)	0.307[m]
Intra-group change p	0.066[w]	0.109[w]	
Social Functioning			
Baseline	62.0 (12-100)	62.0 (20-100)	0.385[m]
After	62.0 (12-100)	62.0 (12-100)	0.589[m]
Baseline-after change	0.0 (0-30)	0.0 (0-30)	0.539[m]
Intra-group change p	0.180[w]	0.109[w]	
Role-Emotional			
Baseline	100.0 (0-100)	100.0 (0-100)	0.626[m]
After	100.0 (0-100)	100.0 (0-100)	0.827[m]
Baseline-After Change	0.0 (0-50)	0.0 (0-30)	0.281[m]
Intra-group Change p	0.317[w]	0.109[w]	
Mental Health			
Baseline	48.0 (32-60)	48.0 (32-60)	0.699[m]
After	52.0 (32-77)	56.0 (32-60)	0.780[m]
Baseline-after change	0.0 (0-31)	0.0 (0-10)	0.502[m]
Intra-group change p	0.053[w]	0.109[w]	

[m]Mann-Whitney U test; [w]Wilcoxon test.

locomotor training following acute SCI was provided by animal experiments indicating that rehabilitation induced plasticity of the spinal locomotor centres. Individuals with complete injury might have gait-like EMG activity when they stepped with body-weight support on a treadmill.[18,19]

Our study was conducted using a control group with similar age, type, duration of injury and lesion level with the patients with complete and incomplete SCI in the subacute period when neurological improvement continues. A significant increase was observed in WISCI scores, used for evaluating functional ambulation, and in FIM scores, used for functional independence. A literature search frequently results in studies on patients with either complete or incomplete spinal injury only. In a study that includes complete and incomplete injury patients, robotic-assisted treatment was administered for 1 hour for two to three times a week for 28 patients, and a significant increase was identified in Spinal Cord Independence Measure scores even though the increase in Functional Ambulation Categories and WISCI scores was not significant compared to the conventional group.[20] In the study by Shin et al. using incomplete injury patients only and robotic-assisted gait training (RAGT) and similar evaluation parameters, the increases in FIM and WISCI II scores were more significant than in the conventional group.[21] Starting time and treatment protocol for RAGT must be discussed. Patients in the subacute period were examined in our study. A total of 16 sessions of treatment were conducted for an 8-week period (two times a week). In a compilation study, studies with two to five sessions per week and a duration of 4-13 weeks in the acute-subacute and chronic periods were evaluated, showing that an approach to recovery of ambulatory function has potential without any superiority of one over the other.[22] In the study by Manella et al., the patient's lower extremity motor score increased, the patient's body and sitting balance developed and the patient was able to walk with a pair of KAFO-Walkers as a result of locomote treatment. It was considered that neuroplastic changes might have been achieved via an intense programme of motor connections protected at lesion level for complete injury patients.[23] In a study where complete injury patients were evaluated via a ReWalk device, it was reported that ReWalk is a safe gait orthosis for the patients with SCI at the motor-complete thoracic level, and that the majority of the patients achieved walking capability at a level close to the level required for limited public ambulation.[24] In another study carried out with complete injury patients, change in ground reaction force was measured at standing and walking phases, and patients had a ground reaction force with similar size and pattern as the individuals in the control group. Accordingly, the researchers considered that mobile exoskeleton support might create the potential for walking by providing mechanical gait for the lower extremities.[25]

Unlike the other studies, SF-36 was used in our study to evaluate the quality of life. Both groups had a significant increase in physical activity scores only. While similar increases were observed in both groups as a result of treatments, there was not any difference in terms of recovery between the two groups. We observed that the patients' quality of life could be increased as a result of increased mobility and functional capacity with robotic-assisted training along with the conventional treatment. The low number of patients, the inclusion of paraplegic-tetraplegic patients in the groups, and checking only early period results and evaluating using a few parameters might be considered as the limitations of our study.

CONCLUSION

We conclude that the data from our study might be useful for robotic gait training that can be provided along with other rehabilitation methods in the early period and in both patients with complete and incomplete SCI. Controlled studies with a larger number of participants are still needed for the purposes of evaluating the different impacts of robotic locomotor therapy on various SCI populations and determining the appropriate protocol.

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