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Original Research

The Effects of Robotic Walking and Activity-Based Training on Bladder Complications Associated with Spinal Cord Injury

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Abstract

Background: Traditional Activity-based Training (ABT) and novel Robotic Locomotor Training (RLT) demonstrate promising results for reducing secondary complications associated with SCI, including bladder dysfunction. However, there is a need for increased evidence through randomised controlled trials (RCTs). This study aimed to determine the effect of RLT compared to ABT on bladder function in individuals with incomplete SCI involved in a pilot randomised controlled trial. **Methods**: Sixteen participants with motor incomplete tetraplegia (>1 year) were recruited. The RLT and ABT involved 60-minute sessions, 3× per week for 24 weeks. The International Lower Urinary Tract Function Basic Data Set was used to assess self-reported bladder health and function over 24 weeks. **Results**: Across participants, intermittent catheterization, either by self or attendant was used by most of the participants (44%), followed by indwelling catheters (31%). No significant group differences were found for the bladder outcomes over time, except for improvements in urinary function (p = 0.04) at week 24. The odds ratio of 0.26, indicated that the RLT group was less likely to have an improvement in bladder function compared to the ABT group. Both groups tended to show a pattern of decreasing urinary incontinence over time. **Conclusions**: The ABT group experienced greater benefits in bladder function, but both groups showed a tendency of decreased urinary incontinence over time. Both RLT and ABT interventions may positively benefit the neural circuitries controlling urogenital functions in persons with SCI. RCTs involving larger sample sizes are warranted to further examine these preliminary results.

Keywords: spinal cord injury; rehabilitation; robotics; exercise; bladder function

1. Introduction

Spinal cord injury (SCI) can result in disrupted autonomic control and a loss in descending modulation and communication between the brainstem and the lumbosacral cord, in turn reducing bladder function [1–3]. Bladder complications following SCI, known as neurogenic bladder dysfunction, include reduced capacity, unwanted retention, poor voiding, increased urinary incontinence and increased risk of urinary tract infections [2]. Neurogenic bladder can be a disturbance for both physical and psychological well-being for individuals with SCI, restricting independence levels and increasing morbidity risk, which in turn has tremendous impacts on quality of life [2,4–6]. Restoration of bladder function is perceived as one of the top priorities for recovery for individuals with spinal cord injury (SCI) [5,7]. Thus, regular monitoring and suitable management for this dysfunction are important to prevent long-term health complications and provide a better quality of life for those with SCI [8,9].

Activity-based training (ABT) currently represents the global standard of care following SCI [10–14]. ABT refers to "interventions that target activation of the neuromuscular system below the level of the lesion, with the goal of retraining the nervous system to recover a specific motor task" [12]. ABT can facilitate general health maintenance [15] and improve autonomic responses, including lower urinary tract functions [2,16]. Regular aerobic and resistance training, components of ABT, can enhance neuromuscular plasticity which has shown to increase bladder capacity and decrease urinary incontinence [17–19]. However, these improvements in autonomic function after ABT have been modest and evidence is limited [1,20]. A recent review highlights the scarcity of research studies focused on recovery of autonomic functions following SCI [21].

Robotic Locomotor Training (RLT), which has been shown as an effective tool for improving post-SCI motor outcomes, could potentially also be used as a management strategy for improving bladder complications [22,23]. Central pattern generators (CPGs) responsible for the synchronization between the flexion and extension of the lower limbs are located in the lower thoracolumbar spine [24]. Bladder function is controlled from the parasympathetic input at S2–S4 spinal segments and sympathetic input at

T10-L2 spinal segments [1]. Therefore, given the existing overlap of the lumbosacral spinal circuitries controlling pelvic-visceral and locomotor functions, RLT may play a role in augmenting bladder function for those with SCI [2]. Furthermore, locomotion activates the pelvic floor muscles, possibly as part of a control strategy to regulate intra-abdominal pressure, in coordination with other muscles of the trunk [25]. During overground walking, which requires weight-shifting to trigger steps, there is activation of trunk muscles [26]. However, during treadmill-based locomotor training, no trunk muscle activation has been observed [26]. Considering that the pelvic floor muscles co-activate with trunk muscles, which are active during locomotor training, together with activated lower CPGs, it is plausible that RLT could prevent urinary incontinence and improve bladder function [27]. However, although RLT serves as a promising therapeutic tool for treating secondary complications after SCI, there is insufficient evidence to draw conclusions about its effectiveness in persons with SCI [28,29]. A strong evidence base for the prevention and effective management of bladder complications will be essential for future breakthroughs in SCI health and well-being. We thus aimed to assess self-reported benefits in bladder functioning during a 24-week rehabilitation intervention in individuals with chronic, incomplete SCI.

2. Methods

2.1 Study Design

Primary outcomes including feasibility measures, functional capacity, and cardiovascular changes have been previously reported from the original pilot RCT [30,31]. Additional measures related to bladder function, not analysed in the original study, were analysed by the authors of this paper as a secondary analysis. Randomisation, via computer generation, was performed by the project manager after participants completed pre-intervention testing. Participants were randomly assigned to two groups receiving different interventions: ABT (n = 8) and RLT (n = 8). Participant informed consent was obtained for the study and for any publication.

2.2 Participants

Participant inclusion criteria were as follows: chronic ($>$1 year) traumatic motor incomplete tetraplegia, individuals 18–65 years, motor incomplete injury (AIS C, D), with a neurological level of injury (NLI) between C1-C8 (tetraplegia), must be reliant upon a wheelchair as the primary mode of mobility, sufficient anthropometrics and range of motion (ROM) to achieve a normal, reciprocal gait pattern within the Ekso GT^{TM} suit, had to be medically stable and cleared by a physician for full weight bearing locomotor training including 15-minute standing frame trial to assess standing tolerance.

Participant exclusion criteria included: non-traumatic SCI, have trained in a robotic exoskeleton in the past 12-months or currently performing any other form of locomotor training, Modified Ashworth Scale (MAS) = 4 in any of the lower extremity joints, skin integrity issues in areas that contact the device, pregnancy, severe osteoporosis, any medical issue that in the opinion of the investigating team precludes full weight bearing locomotor training, including but not limited to: heart or respiratory comorbidity, spinal instability, acute deep vein thrombosis (DVT) with activity restrictions, severe, recurrent autonomic dysreflexia (AD) requiring medical intervention, heterotopic ossification (HO) in the lower extremities resulting in ROM restrictions at the hips or knees, any medical issue that in the opinion of the investigating team would affect participant safety either due to cognitive deficits/impulsivity, intolerance to mild exercise or other factors, any issue that in the opinion of the investigating team would confound results such as a concurrent neurological injury or disorder (other than SCI).

2.3 Rehabilitation Protocol

Detailed methods and protocols have been previously described [30]. Both the RLT and ABT interventions involved training three times per week for 60 minutes per session, over 24 weeks. RLT involved overground walking in the Ekso® GT Variable Assist Model exoskeleton (Ekso Bionics, Richmond, CA, USA). ABT involved a variety of equipment for resistance, cardiovascular, and flexibility training as well as gait retraining (without a treadmill or robotic assistance). Each ABT session was standardised as follows: warm-up and mobility (5 min), resistance training (20–30 min), and cardiovascular training (20–30 min).

The design of this pilot clinical evaluation comprised pre–post assessment of the intervention effect on bladder function. The International Lower Urinary Tract Function Basic Data Set questionnaire [32] was used to assess bladder health and function at baseline, 6 weeks, 12 weeks and 24 weeks of the interventions. Specific categories of this questionnaire included: (a) Urinary method, (b) Bladder medications, (c) Average number of urinations per day (over the last week), (d) Average frequency of urinary incontinence (over the last 3 months), (e) Improvements in bladder function (over the last year).

2.4 Statistics

All data were analysed using statistical software (R, version 3.6.0, R Core Team, Auckland, New Zealand and Prism 8, GraphPad Software Inc, CA USA). Self-reported categorical responses were analysed cross-sectionally using a Fisher’s exact test at each time point over the four testing periods (0, 6, 12 and 24 weeks). In the cases where a response was binary, an odds ratio (OR) of the RLT group to the ABT group was calculated. Significance was accepted at a $p < 0.05$.

Table 1. Baseline descriptive bladder characteristics of the Robotic Locomotor Training and Activity-based Training groups.

Group	Participant	Age (years)	Time since injury (years)	Neurological level of injury	AIS category	Aetiology	Sex	Urinary method	Bladder medication
RLT	1	27	9	C6	D	Stabbing	Male	Normal voiding	None
	2	33	15	C6	C	MVA	Male	Intermittent self-catheterization	None
	3	32	3	C5	D	MVA	Male	Transurethral indwelling	None
	4	46	26	C4	D	Gunshot	Male	Intermittent catheterization by attendant	None
	5	55	4	C5	D	MVA	Male	Normal voiding	None
	6	43	23	C6	C	MVA	Male	Intermittent self-catheterization	Bladder relaxants, sphincter/bladder neck relaxants, antibiotics
	7	56	15	C4	C	MVA	Male	Condom catheter	None
	8	32	15	C7	C	Sport - Rugby	Male	Intermittent self-catheterization	None
	Average	40.5 ± 11.2	13.8 ± 8.2						
ABT	9	26	2	C6	C	MVA	Male	Suprapubic indwelling	None
	10	46	20	C6	D	MVA	Female	Normal voiding	None
	11	50	8	C7	D	MVA	Male	Transurethral indwelling	Bladder relaxants
	12	19	2	C5	C	MVA	Male	Intermittent catheterization by attendant	Bladder relaxants
	13	47	3	C4	D	Motorcycle	Male	Intermittent catheterization by attendant	None
	14	29	10	C5	C	MVA	Male	Suprapubic indwelling	Bladder relaxants, sphincter/bladder neck relaxants, antibiotics
	15	60	2	C5	C	Mountain bike	Male	Intermittent self-catheterization	bladder relaxants, antibiotics
	16	30	11	C4	C	Diving	Male	Transurethral indwelling	Bladder relaxants, antibiotics
	Average	38.4 ± 14.3	7.3 ± 6.4						

RLT, Robotic Locomotor Training (n = 8); ABT, Activity-based Training (n = 8); MVA, motor vehicle accident. Values quoted as mean ± SD. No significant difference between groups for age and time since injury (p = 0.10).

3. Results

The two intervention groups were matched at baseline for age and time since injury (Table 1). Motor vehicle accidents were the most common cause of injury across all participants (63%). Participants had an average adherence to the intervention of 93.9 $\pm$ 6.2% of all available sessions (overall 72 missed of 1152 sessions: 6.25%). Intermittent catheterization, either by self or attendant was used by the majority of the participants (44%) as the chosen urinary method, followed by use of indwelling catheters (31%). Bladder medications were documented at baseline, with no changes in the medication occurring throughout the trial (Table 1).

No significant differences were found in bladder function between the ABT and RLT groups at baseline. Both groups experienced approximately four urinations per day and had monthly urinary incontinence. No significant group differences were found for the bladder outcomes over time, except for improvements in urinary function (p = 0.04). An evaluation of the change in urinary function over all time points showed a significant difference between groups occurring at week 24, as illustrated in the final column of the mosaic plot in Fig. 1A. Fisher's exact test for this time point reported a p-value of 0.04, which suggests that the type of intervention had a significant influence on the odds of urinary change. The odds ratio at this time point was 0.26, indicating that the RLT group was less likely to have an improvement in bladder function compared to the ABT group. Both groups tended to show a pattern of decreasing urinary incontinence over time (Fig. 1B).

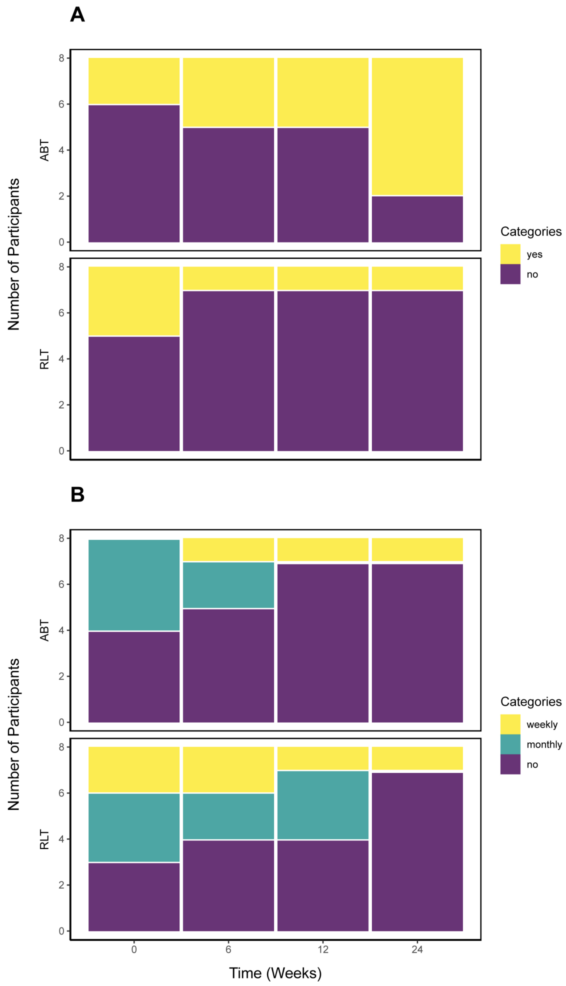

Fig. 1. Results of the International Lower Urinary Tract Function Basic Data Set for the Robotic Locomotor Training and Activity-based Training groups over time. (A) Improvement in urinary function, (B) Frequency of urinary incontinence. RLT, Robotic Locomotor Training (n = 8); ABT, Activity-based Training (n = 8). Improvements in bladder function were taken for the previous year, hence why change can be seen at week 0.

4. Discussion

This study aimed to describe the self-reported effects of ABT and RLT on bladder function in individuals with SCI. Although both interventions appeared to improve urinary incontinence, the ABT group was more likely to experience significant improvements in bladder function compared to the RLT group. These changes were only shown by week 24, highlighting the need to have longer intervention periods to induce improvements in urinary function. Similarly, Morrison *et al*. [33] showed that 120 sessions of bodyweight-supported locomotor training improved bowel, bladder and sexual function by 21–33% and that the greater the dose of intervention, the more meaningful the change in outcome. Another longitudinal intervention, of 80 sessions of arm crank exercise, resulted in a significant improvement in bladder pressure and compliance, but not bladder capacity or voiding efficiency [19]. However, task-specific stepping and loading is required to maximize the sensory input to the spinal cord neural circuitries which control bladder function such as bladder storage and emptying functions [2,19,34,35]. Hubscher *et al.* [2] investigated bladder function in participants (n = 8) undergoing RLT. All participants experienced significant increases in bladder capacity, voiding efficiency, detrusor contraction time and decreased voiding pressure after training compared to baseline.

Various non-activity related factors can also influence bladder function in individuals with SCI including, level of injury, extent of disability/completeness of cord injury, duration of injury and level of care available to the patient [8,9]. Additionally, intake of diuretics and various medications can also affect dysfunction [8,36]. Therefore, both RLT and ABT interventions may positively benefit the neural circuitries controlling urogenital functions in persons with SCI [2,34,35], but effective management should ensure individualized training based on the type of dysfunction, as well as these unique categorizing qualities.

5. Limitations

A limitation of this study lies with the completion of the questionnaires. The accuracy of the responses may have been affected by the participants interpretation and subjective understanding of the questions due to the medical terminology used. In addition, the participants were required to complete the questionnaires in their own time outside of the rehabilitation setting. It is suggested that for future studies, the questionnaires be completed in the rehabilitation setting to avoid possible distractions that may have occurred at home, with the assistance of a research investigator to answer queries if required. In addition to the self-reported data, quantitative measures, such as urodynamics, would be of benefit to enhance the analysis of urinary outcomes after SCI.

6. Conclusions

In conclusion, both interventions, particularly ABT, appeared to aid in reducing urinary incontinence and improving bladder function. Addressing secondary complications and the management thereof, is a priority for individuals with SCI, and thus, should be investigated further with large-scale RCTs.

Author Contributions

All authors (CS, RE, SW, YA, WD) designed the research study, performed the research, and provided support with the study analysis. CS analysed the data andwrote the manuscript. All authors (CS, RE, SW, YA, WD) contributed to editorial changes andread and approved the final manuscript.

Ethics Approval and Consent to Participate

This study is a secondary analysis of a registered pilot RCT (Pan African Clinical Trial Registry-PACTR201608001647143) and obtained ethics approval from the Faculty of Health Sciences Human Research Ethics Committee (HREC 718/2017).

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Conflict of Interest

The authors declare no conflict of interest. A loaner exoskeleton was provided by Ekso Bionics for the duration of the study. Ekso Bionics were not involved in the conceptualisation, design, data analysis, interpretation, or dissemination of the study's results.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/j.jomh1806135.

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