Dionne *et al. Critical Care* (2026) 30:267
https://doi.org/10.1186/s13054-026-06010-z

Critical Care

RESEARCH Open Access

Effects of early acute in-bed leg cycling initiated from the intensive care unit following severe traumatic spinal cord injury: final results from the PROMPT-SCI trial

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Abstract

Background Preclinical studies suggest that initiating activity-based therapy (ABT) within days of an acute spinal cord injury (SCI) best enhances recovery, but may also increase the risk of inducing spinal cord damage. This study assesses the effects of early ABT initiated within 48 h of spinal surgery (or 3 days of the SCI), while patients are in the intensive care unit (ICU) for hemodynamic management.

Methods This single-arm proof-of-concept trial included 45 adults with a severe traumatic SCI receiving daily 30-minute sessions of in-bed leg cycling for 14 consecutive days, in comparison to a matched historical control cohort that did not undergo ABT. Cycling was initiated in the ICU within 48 h of spinal surgery. The main patient outcome was the recovery of independent walking 6 months post-SCI. Secondary outcomes included the rates of complications and other neurofunctional assessments.

Results Recovery of independent walking occurred in 31% of PROMPT-SCI participants and 36% of controls ($p=0.3$). Neurological recovery was similar between the two cohorts. The PROMPT-SCI cohort had decreased spontaneous spams (9% vs. 40%, $p<10^{-3}$) and co-occurrence of pneumonia, pressure injury and urinary tract infection (P/UTI/PI) (2% vs. 13%, $p=0.03$). Readiness for rehabilitation transfer was decreased by 7 days in the PROMPT-SCI cohort, approaching statistical significance ($p=0.051$). When adjusting for baseline motor score, spontaneous spasms remained decreased with ABT ($p=0.001$; odds ratio = 0.14 [95%CI: 0.04–0.45]), and rehabilitation transfer readiness was shorter ($p=0.03$; β=-0.22 [95%CI: -0.41 – -0.04]). However, there was no significant association between concomitant P/UTI/PI and ABT ($p=0.08$; Odds ratio = 0.14 [95%CI: 0.02–1.24]).

Conclusions Early acute ABT did not increase the risk for neurological deterioration when initiated in the ICU for patients requiring hemodynamic management. It can decrease the early occurrence of spontaneous spasms, and may potentially reduce the co-occurrence of P/UTI/PI and accelerate rehabilitation transfer readiness.

Trial registration ClinicalTrials.gov identifier NCT04699474 (Registration Date: January 5th 2021).

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Introduction

Preclinical evidence suggests that there is a window of opportunity extending from a few days to a few weeks after a SCI during which introducing activity-based therapy (ABT) is most effective for enhancing neurofunctional recovery [1]. There is also strong evidence that early mobilization of patients in the intensive care unit (ICU) or after spinal surgery improves the course of care, decreases complications, and accelerates recovery in a wide variety of patient subgroups without SCI [2, 3]. However, patients with severe SCI remain mostly bedridden and comparatively immobile throughout acute care, particularly when they are in the ICU for monitoring and hemodynamic management after spinal surgery. Immobilization limits neurofunctional recovery after SCI [4, 5] and increases the risks of complications. Early acute ABT initiated within the first few days of a severe SCI has never been attempted clinically. In addition, clinicians remain fearful that early and aggressive mobilization after an acute SCI might exacerbate spinal cord damage and impair neurological recovery if started too early [6], subsequent to an animal study showing that swimming introduced three days post-SCI in rats appeared to exacerbate spinal microvascular dysfunction while the blood-spinal cord barrier is disrupted. To address these gaps, we have designed the PROMT-SCI (Protocol for Rapid Onset of Mobilization in Patients with Traumatic SCI) trial, the first ever human trial of early acute ABT initiated within 48 h of spinal surgery [7–9]. This study reports the complication rates and long-term neurofunctional recovery of 45 participants of the PROMPT-SCI trial 6 months following the injury in comparison to a retrospective matched control cohort.

Methods

Study participants

Forty-five adult patients were recruited from a single Level 1 trauma center in Montreal, Canada (Hôpital du Sacré-Coeur de Montréal) between April 2021 and August 2023. To be included in this single-arm proof-of-concept trial, patients were required to meet the following criteria: (1) age 18 years or older; (2) traumatic SCI with American Spinal Injury Association Impairment Scale (AIS) grade A, B or C; (3) neurological level of injury (NLI) between C1 and L1; (4) blunt (non-penetrating) trauma causing the SCI; and (5) spinal decompression surgery performed ≤ 48 h of the injury. Patients were excluded if they presented one of the following criteria: (1) a condition limiting the patient's ability to engage in cycling (e.g. pelvis or lower extremity injury or deformity, body mass index >35 kg/m^2, etc.); (2) a medical contraindication to cycling as determined by caring teams (e.g. hemodynamic instability, active myocardial infarction, etc.); (3) moderate or severe traumatic brain injury; (4) complete spinal cord transection confirmed by MRI and/or during surgery; (5) unwillingness or inability to comply with follow-up; or (6) pre-existing medical condition impairing walking ability (e.g. prior neurological disease, lower limb anomaly). All participants provided informed written consent before enrollment. The study (#2020 – 1901) was approved by the local institutional review board.

Acute care

All participants received the usual standard of acute care for SCI [10] from a specialized neurotrauma team composed of spine surgeons, acute care physiatrists, intensive care physicians, specialized nurses, and allied health professionals. Early decompressive spinal surgery – within 24–48 h of the SCI – is usually performed to minimize the secondary injury. After surgery, patients are transferred to the ICU for monitoring and maintenance of mean arterial pressure (MAP) ≥ 85 mmHg for 7 days, using vasopressors if needed.

The principles for prevention, diagnosis and management of complications are aligned with the guidelines set by the Consortium for Spinal Cord Medicine Clinical Practice Guidelines before the time period involved in this study [10–13]. Specifically for catheter management, we install a transurethral bladder catheter in the emergency department as soon as a severe SCI is suspected. After surgery, bladder dysfunction is managed according to a systematic trial of void protocol [14]. To prevent pressure injuries, all patients with severe SCI benefit from a therapeutic bed, systematic pressure injury risk assessment and daily skin inspection, and are repositioned in side-lying position by the caregivers every two hours while in bed. In addition to the strict monitoring for respiratory failure in the intensive care unit after surgery for severe SCI, patients are mobilized daily in a wheelchair or reclining chair whenever it is tolerated, starting the day after surgery. Also starting the day after surgery, our routine protocol for physical therapy consists of 15 min sessions 6 times/week of passive mobilization of paralyzed joints for the first 2 weeks, followed by 30 min sessions 4 times/week focusing on antigravity strengthening and postural exercises. Occupational therapy sessions are delivered two days/week or more as needed. Outside the PROMPT-SCI trial, ABT is not included in the care standards at our institution nor in our affiliated rehabilitation facility where patients are transferred following acute care.

PROMPT-SCI intervention

The early acute ABT protocol consisted of daily 30-minute sessions of continuous in-bed leg cycling for 14 consecutive days, starting within 48 h of spinal surgery while in the ICU, as soon as patients are deemed medically

stable. Prior to every session, participants were screened to assess their fitness to engage in cycling (Table 1). The ergometer used to perform cycling sessions was the APT-5 ergometer (Tzora Active Systems, Ohio, USA). Participants pedaled at a cadence of 40 revolutions per minute to replicate a low-normal step frequency during walking. Participants achieved this cadence with limited assistance (active-assisted cycling) or total assistance (passive cycling). The motor output was titrated according to their motor strength to reach the target cadence. During sessions, heart rate, MAP, respiratory rate and blood oxygen saturation were closely monitored by a research assistant – not involved in care or data analysis – who remained at the bedside. Adverse events were noted and reported to the principal investigator. Sessions were stopped if participants or the caring team requested termination, if vital signs fluctuated outside of the following ranges in a sustained fashion: MAP: 60–110 mmHg; HR: 40 – 140 bpm; SpO2: ≥90%, or if there were signs of medical instability (Table 1). After each session, the neurological status was assessed in accordance with the International Standards for the Neurological Classification of Spinal Cord Injuries (ISNCSCI).

Table 1 Daily exemption and ceasing criteria

Daily exemption criteria	Stopping criteria
In-bed leg cycling should not be delivered if:	*In-bed leg cycling should cease if:*
Caring team determines that patient is hemodynamically or medically unstable	Sustained or symptomatic heart rate <40 or >140 bpm[a +]
Resting heart rate <40 or >140 bpm[+]	New arrhythmia
Unstable or uncontrolled arrhythmia	Concern for coronary ischemia (e.g. chest pain, changes on electrocardiogram)
Active coronary ischemia	Sustained or symptomatic mean arterial pressure <60 or >110 mm Hg
Mean arterial pressure <60 or >110 mm Hg	Unplanned extubation or endotracheal tube dislodgment
SpO_2 <90%	Sustained SpO_2 <90%
Pressure ulcer at sacrum, buttock or heel area grade ≥2*	Clinical signs of cardiorespiratory distress
Severe agitation[a]	Severe agitation[a]
Uncontrolled pain	Termination of in-bed cycling session requested by patient or caring team
Caring team considers that in-bed cycling is not appropriate for a condition other than above criteria (e.g. active bleeding, incision or wound precluding cycling, risk of compartment syndrome, etc.)	
Patient refuses in-bed cycling	

[+]bpm: beats per minute

*According to the pressure injury staging system of the National Pressure Ulcer Advisory Panel

[a]With a Richmond Agitation and Sedation Scale >2

Control cohort

A historical control cohort was retrieved from our local prospective database of 700 + patients admitted for a traumatic SCI between August 2010 and March 2021. These patients received the same acute and rehabilitative care as described previously, but did not receive ABT during acute care or inpatient rehabilitation phase. All patients meeting the inclusion criteria of the PROMPT-SCI trial described above were considered. After applying the exclusion criteria, a total of 101 potential control patients remained. They were matched to PROMPT-SCI trial participants with an allocation ratio of 1:1 based on the following variables: AIS grade (A vs. B vs. C), NLI (C1-C4 vs. C5-T1 vs. T2-T8 vs. T9-L1), age, and sex (male vs. female). Matching without replacement was used. AIS grade, NLI and sex were hard criteria prioritized in the matching process (meaning that a potential control was required to be an exact match on these criteria to be considered as a match candidate). An optimal matching technique based on nearest-neighbor logic (i.e. potential control with age at injury closest to trial participant chosen as matched control) was used to minimize the total absolute distance across all pairs in the dataset for age.

Patient outcomes

Neurofunctional recovery was assessed at follow-up between 6 and 12 months following the trauma. The primary patient outcome consisted of the recovery of independent walking ability assessed from Item 12 (Mobility indoors) of the 3rd version of the Spinal Cord Independence Measure (SCIM), and was defined by a score 4 or higher [15]. The SCIM assesses functional independence from the ability to perform daily living activities of self-care (subtotal score 0 to 20), respiration and sphincter management (subtotal score 0 to 40), and mobility (subtotal score 0 to 40) [16].

Neurological recovery was assessed by the changes in AIS grade, NLI, total motor score, light touch score and pinprick sensory score from baseline to follow-up assessment according to the ISNCSCI. Clinically significant neurological improvement was defined by an improvement by at least one AIS grade, two NLI or five points in total motor score, light touch score or pinprick score.

Complications most commonly observed after SCI were collected throughout acute care for pneumonia, urinary tract infection, pressure injury and early spasticity. Urinary tract infection are diagnosed using criteria from the 2006 Consortium for Spinal Cord Medicine Clinical Practice Guidelines, based on the presence of significant bacteriuria, pyuria, and signs and symptoms of urinary tract infection [11]. The presence of pressure injuries are diagnosed according to the National Pressure Ulcer Advisory Panel system, based on the recommendations from

the 2001 Consortium for Spinal Cord Medicine Clinical Practice Guidelines [12]. The presence of pneumonia is diagnosed using clinical features and needs to be confirmed by a radiologist using chest radiographs [13].

The occurrence of early spasticity during the acute hospitalization was identified if any of the following signs were identified: 1- increased velocity-dependent muscle tone at physical examination (Modified Ashworth scale [17] score 1 or higher); 2- spasms upon physical examination and/or reported by the patient, or 3- clonus noted at physical examination and/or reported by the patient. The frequency with which spontaneous spasms occur during acute care was assessed using the self-reported Penn Spasm Frequency Scale [18], and the presence of spontaneous spasms was determined by a score 2 or higher.

The acute length of stay was noted for those living through acute care. Because the length of stay is also influenced by the wait time for transferring to our affiliated inpatient rehabilitation center, we also collected the rehabilitation transfer readiness, defined as the time (days after SCI) when the patient is deemed ready for transfer, based on the following criteria: (1) patient demonstrates motivation to participate in intensive functional rehabilitation, (2) patient requires continuation of at least two types of therapy (e.g. physical therapy, occupational therapy, psychology, etc.), (3) medical stability has been reached without ongoing investigation or treatment required at the acute center, and (4) patient can tolerate at least 60 min/day of active therapies. The rehabilitation transfer readiness corresponds to the potential minimum length of stay at our acute center if there was no wait or delay before transferring to the rehabilitation center. Rehabilitation transfer readiness was determined by consensus from the multidisciplinary SCI team of our acute center that includes the attending spine surgeon, physiatrist, physical therapist, occupational therapist, as well as the liaison nurses and nurse practitioners. The criteria for rehabilitation transfer have been established in agreement with our affiliated intensive functional rehabilitation center.

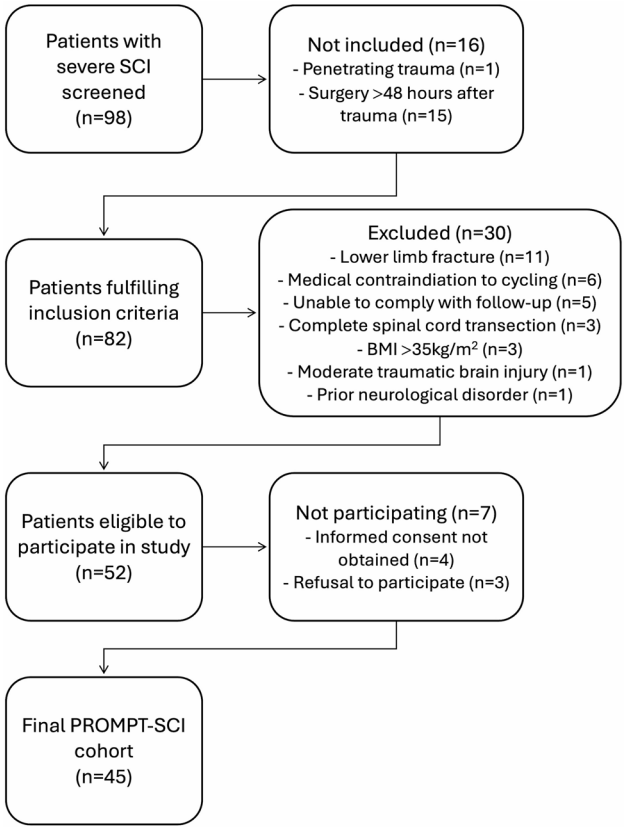

Fig. 1 Flowchart of PROMPT-SCI trial participants

Statistical analysis

A sample size estimation of 45 participants for each cohort has already been established for the PROMPT-SCI trial, while accounting for potential 20% dropout rate [9]. Data were analyzed and reported using intention-to-treat principles, considering that satisfactory adherence to the planned protocol was achieved for the trial by reaching the feasibility outcomes [7]. All statistics were performed using SPSS v. 27 (IBM, Chicago, IL, USA) with a level of significance of 0.05. Descriptive statistics were first used to characterize the PROMPT-SCI and control cohorts. Baseline characteristics – including variables not used in the matching process – were compared to assess the quality of matching. Patient outcomes were compared between the two cohorts using one-tail McNemar and paired Student's t-tests for binary and continuous patient outcomes, respectively. Chi square tests were used to compare variables with more than two categories. Cohen's *d* statistic with 95% confidence interval for continuous variables and odds ratio (OR) with 95% confidence interval for proportions are used to describe the comparisons in baseline characteristics and outcomes.

Considering that the total motor score can vary widely, even for individuals with similar NLI and AIS grade, regression analyses were performed secondarily to further investigate the association between patient outcomes and early acute ABT, while adjusting for baseline total motor score. Odds ratios and β coefficients with 95% confidence interval were reported for logistic and linear regressions, respectively.

Results

A flowchart describing the recruitment process is available in Fig. 1. During the study period, 102 adult patients presented with a suspected acute severe traumatic SCI of AIS grade A, B or C, and a NLI comprised between C1 and L1. A total of 98 patients were screened, while four were excluded before screening because a reliable baseline neurological examination could not be obtained for

these patients to confirm the presence of a SCI. Of these patients, 16 did not fulfill the inclusion criteria (one penetrating trauma causing the SCI and 15 undergoing surgery more than 48 h after the trauma), and 30 were excluded. Informed consent could not be obtained in four patients, and three patients refused to participate in the study.

The baseline characteristics of the cohorts are described in Table 2. There were no significant differences observed between the two cohorts for any of the baseline variables collected (Table 2). Comparisons in acute outcomes are presented in Table 3. There were consistent trends in decreasing rates of pneumonia (35.6% vs. 40.0%, $p=0.31$), urinary tract infection (17.8% vs. 28.9%, $p=0.10$), and pressure injuries (33.3% vs. 46.7%, $p=0.11$) in the PROMPT-SCI cohort. There was a significant difference in the proportion of participants sustaining concomitant pneumonia, urinary tract infection and pressure injury (2.2% vs. 13.3%, $p=0.03$). Among discordant pairs, there were 6 pairs for which these complications were seen concomitantly only in controls, and 1 pair for which they were seen concomitantly only in the PROMPT-SCI participants (OR = 6.00, 95% CI [0.72–49.84]).

The overall rate of early spasticity (71.1% vs. 73.3%, $p=0.40$) was similar between the two groups. The occurrence of spontaneous spasms during acute care was significantly reduced in the PROMPT-SCI cohort (8.9% vs. 40.0%, $p<10^{-3}$). Among discordant pairs, there were 16 pairs for which spontaneous spasms were seen only in controls, and 2 pairs for which spontaneous spasms were seen only in PROMPT-SCI participants (OR = 8.00, 95% CI [1.84–34.79]). Acute length of stay was reduced by about 6 days in the PROMPT-SCI cohort, without reaching statistical significance ($p=0.13$). Readiness for rehabilitation transfer was decreased by 7 days in the PROMPT-SCI cohort, approaching statistical significance ($p=0.051$, Cohen's $d=0.26$, 95% CI [−0.05–0.56]).

Follow-up was obtained in 39 (86.7%) participants from the PROMPT-SCI trial, while three died within 6 months of the trauma and three were lost to follow-up. Three participants (two C4 AIS grade A and one C5 AIS grade A) decided to stop all treatments due to the severity of their SCI, before deceasing during acute care. There were no differences in the recovery of independent walking ability between the PROMPT-SCI and control cohorts (30.8% vs. 35.9%, $p=0.3$, OR = 3.50, 95% CI [0.73–16.85]). There were no differences observed between the cohorts in the other neurofunctional outcomes (Table 4).

Results from the multivariable regression analyses adjusting for baseline total motor score are shown

Table 2 Bivariate comparison of long term neurofunctional outcomes for the ROMPT-SCI and matched control cohorts

Characteristic	PROMPT-SCI cohort (*n*=45)	Matched control cohort (*n*=45)	*P*-value	Cohen's d [95% CI]	Odds ratio [95% CI]
Sex					
Male	40 (88.9%)	40 (88.9%)	-	-	-
Female	5 (11.1%)	5 (11.1%)			
Age	53.2±18.7	53.4±17.3	0.48	0.01 [−0.28–0.30]	-
AIS[a] grade					
A	26 (57.8%)	26 (57.8%)	-	-	-
B	9 (20.0%)	9 (20.0%)			
C	10 (22.2%)	10 (22.2%)			
NLI[b]					
C1-C4	12 (26.7%)	12 (26.7%)	-	-	-
C5-T1	16 (35.6%)	16 (35.6%)			
T2-T8	3 (6.7%)	3 (6.7%)			
T9-L1	14 (31.1%)	14 (31.1%)			
AIS motor score	31.8±20.5	34.7±25.7	0.14	0.16 [−0.13–0.45]	-
AIS light touch score	61.2±27.6	58.2±29.0	0.18	−0.14[−0.44–0.16]	-
AIS pinprick score	58.9±29.2	55.3±28.0	0.13	−0.18[−0.48–0.13]	-
Mechanism of injury					
% Sports	1 (2.2%)	3 (6.7%)		-	-†
% Assault blunt	0 (0.0%)	3 (6.7%)			
% Fall	29 (64.4%)	25 (55.6%)	0.89*		
% Transport	13 (28.9%)	14 (31.1%)			
% Other	2 (4.4%)	0 (0.0%)			
Timing of surgery (hours)	23.7±18.5	21.5±9.7	0.24	−0.11 [−0.40–0.19]	-

[a]American Spinal Injury Association Impairment Scale

[b]Neurological Level of Injury

*Likelihood ratio test performed because >20% of cells in crosstab contained an expected value of less than 5 and crosstab larger than 2x2

†Not computed in the presence of empty cells

Table 3 Bivariate comparison of acute outcomes for the PROMPT-SCI and matched control cohorts

Outcome	PROMPT-SCI cohort (*n*=45)	Matched control cohort (*n*=45)	*P*-value	Cohen's d [95% CI]	Odds ratio [95% CI]
Pneumonia					
Yes	16 (35.6%)	18 (40.0%)	0.31	-	1.30 [0.48–3.45]
No	29 (64.4%)	27 (60.0%)			
UTI[a]					
Yes	8 (17.8%)	13 (28.9%)	0.10	-	2.00 [0.68–5.85]
No	37 (82.2%)	32 (71.1%)			
PI[b]					
Yes	15 (33.3%)	21 (46.7%)	0.11	-	1.67 [0.73–3.81]
No	30 (66.7%)	24 (53.3%)			
Pneumonia & UTI & PI					
Yes	1 (2.2%)	6 (13.3%)	0.03	-	6.00 [0.72–49.84]
No	44 (97.8%)	39 (86.7%)			
Acute spasticity					
Yes	32 (71.1%)	33 (73.3%)	0.40	-	1.14 [0.41–3.15]
No	13 (28.9%)	12 (26.7%)			
Spontaneous spasms					
Yes	4 (8.9%)	18 (40.0%)	$<10^{-3}$	-	8.00 [1.84–34.79]
No	41 (91.1%)	27 (60.0%)			
Acute length of stay (days)	29.5±16.7	35.8±25.1	0.10	0.20 [−0.10–0.49]	-
Rehabilitation transfer readiness (days)	18.0±15.8	25.1±22.0	0.051	0.26 [−0.05–0.56]	-

[a]Urinary tract infection

[b]Pressure injury

in Table 5. In particular, the likelihood for developing early spontaneous spasms during acute care was decreased with ABT ($p=0.001$; Odds ratio = 0.14 [95%CI: 0.04–0.45]). In addition, there was a significant association between ABT and shorter rehabilitation transfer readiness ($p=0.03$; $\beta=-0.22$ [95%CI: −0.41 – −0.04]). As opposed to the result from the matched comparison, the multivariable analysis did not show any significant association between concomitant pneumonia/urinary tract infection/pressure injury and ABT ($p=0.08$; Odds ratio = 0.14 [95%CI: 0.02–1.24]).

Discussion

This study presents the patient outcomes of the PROMPT-SCI trial, which is the first human trial of early acute ABT after traumatic SCI [9]. It lays the foundation for future efforts to optimize and refine the use of early acute ABT as a mean to harness plasticity and improve the recovery after traumatic SCI. However, the risk of inducing further spinal cord damage with ABT introduced within 48 h of spinal surgery – or within 72 h of the SCI – after a severe SCI remains the principal limitation to its clinical implementation, while the blood-spinal cord barrier is disrupted early after the injury [6]. This potential risk of early acute ABT for the SCI population parallels the poor outcomes that can be observed when exercise therapy is started too early and/or at too high an intensity after acute neurological injuries such as stroke [19].

There was no increase in the risk of acute complications nor evidence of long-term neurofunctional deterioration observed in the PROMPT-SCI cohort. This finding supports that early acute ABT involving daily sessions of in-bed leg cycling is not detrimental to neurofunctional recovery when initiated within three days of a SCI, while patients are in the intensive care unit for hemodynamic management. Surprisingly, our trial did not result in a significant improvement in any of the 6-month neurofunctional outcomes, although animal studies showed that the sensory afferent input from early acute ABT – even when performed passively in the presence of complete paralysis – can effectively activate spinal circuitry and promote neurofunctional recovery [20]. Similarly, a recent animal study showed electromyographic activity

Table 4 Bivariate comparison of long term neurofunctional outcomes for the PROMPT-SCI and matched control cohorts

Outcome	PROMPT-SCI cohort (n=39)	Matched control cohort(n=39)	P-value	Cohen's *d* [95% CI]	Odds ratio [95% CI]
Neurological outcomes					
Improvement ≥1 AIS grade					
Yes No	20 (51.3%) 19 (48.7%)	21 (53.8%) 18 (46.2%)	0.40	–	1.13 [0.43–2.92]
Improvement ≥2 segments NLI					
Yes No	6 (15.4%) 33 (84.6%)	6 (15.4%) 33 (84.6%)	0.50	–	1.00 [0.29–3.45]
Improvement ≥5 points on total motor score					
Yes No	23 (59.0%) 16 (41.0%)	25 (64.1%) 14 (35.9%)	0.28	–	1.40 [0.44–4.41]
Improvement ≥5 points on light touch score					
Yes No	21 (53.8%) 18 (46.2%)	23 (59.0%) 16 (41.0%)	0.33	–	1.22 [0.51–2.95]
Improvement ≥5 points on pinprick score					
Yes No	18 (46.2%) 21 (53.8%)	20 (51.3%) 19 (48.7%)	0.33	–	1.22 [0.51–2.95]
Functional outcomes				–	–
SCIM subtotal score					
- Self-care	13.6±7.9	13.1±6.7	0.34	−0.07 [−0.38–0.25]	–
- Respiration and sphincter management	28.4±10.7	26.4±10.8	0.20	−0.14 [−0.45–0.18]	–
- Mobility	17.6±14.2	17.7±11.6	0.50	0.002 [−0.31–0.32]	–
Independent walking (SCIM item 12 ≥4)					
Yes No	12 (30.8%) 27 (69.2%)	14 (35.9%) 25 (64.1%)	0.28	–	3.50 [0.73–16.85]

Table 5 Mutlivariable regression analysis adjusting for baseline total motor score

Outcome vs. activity-based therapy	P-value	*b*coefficient [95% CI]	Odds ratio [95% CI]
Pneumonia	0.53	–	0.73 [0.27–1.95]
Urinary tract infection	0.20	–	0.52 [0.19–1.42]
Pressure injury	0.19	–	0.56 [0.24–1.32]
Pneumonia & Urinary tract infection & Pressure injury	0.08	–	0.14 [0.02–1.24]
Acute spasticity	0.55	–	0.73 [0.26–2.02]
Spontaneous spasms	0.001	–	0.14 [0.04–0.45]
Acute length of stay	0.10	−0.17 [−0.39–0.03]	–
Rehabilitation transfer readiness	0.03	−0.22 [-0.41 - -0.04]	–
Improvement ≥1 AIS grade	0.82	–	0.90 [0.38–2.15]
Improvement ≥2 segments NLI	0.79	–	1.18 [0.35–4.01]
Improvement ≥5 points on total motor score	0.56	–	0.77 [0.31–1.87]
Improvement ≥5 points on light touch score	0.67	–	0.83 [0.34–1.98]
Improvement ≥5 points on pinprick score	0.93	–	0.96 [0.40–2.28]
SCIM Self-care subscore	0.11	0.13 [−0.03–0.27]	–
SCIM Respiration and sphincter management subscore	0.11	0.16 [−0.04–0.34]	–
SCIM Mobility subscore	0.61	0.05 [−0.15–0.26]	–
Independent walking	0.86	–	0.91 [0.33–2.50]

in the hindlimbs of rats performing motorized cycling after a T10 transection, suggesting the presence of spinally mediated muscle activation caused by stretch reflexes below the level of the lesion [21].

We believe that the lack of significant improvement in the neurofunctional outcomes might be partly explained by two reasons. Firstly, neuroplasticity and recovery processes after SCI depend on residual neural pathways spared from the injury. Despite the similar characteristics of their clinical lesion (AIS grade and NLI) between the PROMPT-SCI and control cohorts, we cannot guarantee that the two cohorts were similar in terms of their anatomical lesion (i.e. injured vs. spared neural tissue), which inherently affects the potential of ABT to activate residual neural pathways and promote recovery. Secondly, it is possible that not all individuals will respond to early acute ABT. Whether non-responsiveness in some individuals was due to an insufficient intensity of stimulation (i.e. daily 30-minute sessions or the 14-day protocol being too short, not enough sensory feedback from plantar pressure, joint proprioception or muscle stretching during cycling sessions, etc.), insufficient or inadequate residual neural pathways to achieve effective neuromodulation, or lack of cellular, molecular or genetic adaptations for harnessing adaptive neuroplasticity, cannot be answered by this study. However, these assumptions strongly suggest that future studies on early acute ABT should strive to assess the residual neural pathways and monitor the immediate neurophysiological responses to ABT to isolate its effects, in order to identify responders vs. non-responders and adjust/refine the ABT parameters (modality, intensity, duration, frequency, timing, etc.).

Patients developing early spasticity during acute care, particularly during the first month after a traumatic SCI, have poorer functional outcome and mobility, and

require prolonged inpatient rehabilitation to reach their functional goals [22]. Spasticity after SCI is usually recognized as a sign of maladaptive neuroplasticity (i.e. associated with poor neurofunctional recovery) [23], and may represent a key clinical measure of the early neurological benefits of acute ABT. This study mainly showed that the early onset of spontaneous spasms during acute care was significantly reduced in the PROMPT-SCI cohort, suggesting that initiating early acute ABT within days of a SCI may potentially decrease maladaptive plasticity after the SCI. Comprehensive longitudinal assessment of spinal cord reflex activity could help to determine whether extending early ABT beyond the 14-day duration used in the PROMPT-SCI trial can further harness plasticity and improve the neurofunctional outcomes.

There was a consistent tendency for decreasing complications in pneumonia, urinary tract infection and pressure injury in the PROMPT-SCI cohort. While the matched comparisons resulted in a the significant decrease in the co-occurrence of pneumonia, urinary tract infection and pressure injury with early acute ABT (1 individual in PROMPT-SCI cohort vs. 6 in control cohort), the association was lost after adjusting for baseline total motor score. There could potentially be a temporal bias leading to different complication rates between the two cohorts, although the care standards for prevention of acute complications have not changed significantly since 2010 at our institution. Studies involving larger cohorts and/or other ABT protocols are therefore required to further investigate the impact of early acute ABT on complications for patients with severe SCI – who are mostly bedridden –, knowing that the literature clearly suggests that early mobilization of patients in the ICU or after spinal surgery decreases complications in non-SCI patients [2, 3]. Being able to decrease the rate of complications could contribute to optimize neurofunctional recovery, since the occurrence of infections and pressure injuries has been associated with poorer neurofunctional recovery after SCI [24, 25]. Proposed mechanisms of the neurological insult secondary to complications include a worsening spinal cord ischemia and/or damage from an increase in metabolic rate, an activation of inflammatory cells, a sustained blood-brain barrier disturbance, as well as an interference with mechanisms of neuroplasticity due to the triggered systemic immunological responses. Although not statistically significant, the consistent decrease in the individual rates of pneumonia, urinary tract infection and pressure injury are in agreement with several studies showing a reduction of immobility-related complications with early mobilization in critical ill patients and in patients undergoing elective spinal surgery [2, 3, 26–28]. It is known that even moderate physical activity performed at low intensity can stimulate the immune system and result in improved immune responses to pathogens [29], which could be an important benefit to SCI individuals considering that they typically have a neurogenic immune deficiency after the injury [30]. Passive leg cycling in SCI individuals has been shown to impact the respiratory system with regard to pulmonary ventilation and oxygen uptake [31], which in turn may influence the risk for developing pneumonia. Decreased pulmonary atelectasis and increased mucociliary clearance has also been observed with early mobilization of critically ill patients [3]. In addition, it is possible that cycling alleviates the long periods of urinary stasis due to prolonged bedrest, which predisposes the patient to bacterial growth and urinary tract infection [32]. The results also suggest that the shear stresses that are potentially increased at the sacral region with the semi-inclined position and pedaling motion during the sessions do not increase the risk of pressure injury. To the contrary, the rate of pressure injuries was decreased by more than 10% in the PROMPT-SCI cohort. Whether the pedaling motion causes alternating pressure relief at the sacral area that improves sacral skin blood perfusion and reduces the risk of pressure injury needs to be further investigated.

When adjusting for baseline total motor score, performing ABT was independently associated with shorter readiness for rehabilitation transfer. It is possible that the overall tendency for decreasing acute complications in terms of pneumonia, urinary tract infection and pressure injury may partly explains the shorter readiness for rehabilitation transfer observed in the PROMPT-SCI cohort, similar to other studies showing shorter length of stay with early mobilization in critical ill patients and patients undergoing elective spinal surgery [2, 3, 26–28]. In line with our institutional criteria for determining if patients are deemed ready for transfer to intensive functional rehabilitation, we suggest that well tolerating and appreciating in-bed leg cycling early after the injury – ≥80% of individuals will complete a full session within 48 h of the surgery[7] – may potentially increase the motivation of patients to engage into additional therapies during intensive functional rehabilitation. While conventional physical therapy during the early acute phase following a severe SCI primarily consists of passive mobilization of paralyzed joints,[10] introducing early acute ABT while still in the ICU may also represent a more effective way to improve the activity tolerance of patients, so they may reach more rapidly the transfer criteria of tolerating at least 60 min/day of active therapies.

The authors recognize that there are limitations to the PROMPT-SCI trial. As mentioned previously, we cannot guarantee that the PROMPT-SCI and matched control cohorts share the same anatomical lesions in the spinal cord – and same spared neural tissue –, despite having similar clinical characteristics, which could influence

the results, particularly when comparing the neurofunctional outcomes. Although the care standards have not changed significantly between the time periods for which the control and PROMPT-SCI cohorts were treated, the authors acknowledge that there may be a potential temporal bias limiting the conclusions. A prospective randomized trial is therefore advised in the future to further examine the clinical benefits of early acute ABT. Future studies should also examine the potential benefits of early acute ABT observed in animal studies that were not considered in the current trial, such as a decrease in neuropathic pain or improvement in autonomic function. In addition, our study is a proof-of-concept trial and the optimal parameters of use for early acute ABT may not be those proposed in the PROMPT-SCI trial, and further investigation is needed prior to widespread clinical implementation.

The PROMPT-SCI trial provides key insights into the potential benefits and challenges of early acute ABT after traumatic SCI, opening the door for future studies focused on refining, optimizing and expanding the approach to uncover additional benefits and/or drawbacks. Overall, this study suggests that early acute ABT in the form of in-bed leg cycling does not increase the risk of neurological deterioration if introduced daily within 48 h of spinal surgery (or within 72 h of SCI), even when the patient are in the ICU for hemodynamic management. Conversely, early acute ABT may potentially alleviate maladaptive plasticity as it decreases the occurrence of early spontaneous spasms during acute care. Early acute ABT may also help to accelerate rehabilitation transfer readiness and decrease the co-occurrence of pneumonia, urinary tract infection and pressure injury.

Author contributions

A.D. was involved in data curation, formal analysis, investigation, methodology, validation, writing original draft, and reviewing & editing manuscript. D.S.K.M. was involved in conceptualisation, formal analysis, funding acquisition, investigation, methodology, validation, and reviewing & editing manuscript. A.R.D. was involved in conceptualisation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, supervision, validation, and reviewing & editing manuscript. F.B. was involved in conceptualisation, formal analysis, funding acquisition, investigation, methodology, resources, and reviewing & editing manuscript. D.B. was involved in conceptualisation, formal analysis, funding acquisition, methodology, and reviewing & editing manuscript. Yvan Petit was involved in conceptualisation, formal analysis, funding acquisition, methodology, supervision and reviewing & editing manuscript. J.M.M.T. was involved in conceptualisation, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, supervision, validation, writing original draft, and reviewing & editing manuscript.

Funding

This study was funded by a grant from the Craig H. Neilsen Foundation. The funding source did not have any role in the writing of the manuscript or the decision to submit it for publication. The funding source did not have any role in any aspect pertinent to the study such as data collection, analysis, or interpretation, trial design, patient recruitment, etc.

Data availability

The dataset supporting the conclusions of this article is not publicly available. However, the dataset will be made available to others upon reasonable request, and with permission from our Ethics committee.

Declarations

Ethics approval

This study was approved by the *Comité d'Éthique de la recherche du CIUSSS du Nord-de-L'Île de Montréal* ("Mobilisation précoce suite à une lésion médullaire", study #2020 – 1901, approved on March 12th, 2020) and was conducted in accordance with the principles of the Declaration of Helsinki.

Consent to participate

All patients were recruited on a voluntary basis and provided informed written consent before enrollment.

Competing interests

AD received scholarships from Fonds de recherche du Québec – Santé, Université de Montréal, Institut TransMedTech and CIUSSS Nord-de-l'Île-de-Montréal.DSKM received research funds from the National Institutes of HealthARD received research funds from Medline Industries, Praxis Spinal Cord Institute, Canadian Institutes of Health Research, Craig H. Neilsen Foundation, Fonds de recherche du Québec, and New Frontiers in Research Fund. She received a salary support from Fonds de recherche du Québec – SantéFB received research funds from Canadian Institutes of Health Research and Fonds de recherche du Québec – Santé.DB received research funds from Canadian Institutes of Health Research and Fonds de recherche du Québec – Santé. She received a salary support from Fonds de recherche du Québec – SantéYP received research funds from the Natural Sciences and Engineering Research Council of Canada and New Frontiers in Research FundsJMMT received research funds from Asahi Kasei Pharma Corporation, AbbVie Corporation, Medline Industries, Praxis Spinal Cord Institute, Canadian Institutes of Health Research, Craig H. Neilsen Foundation, Fonds de recherche du Québec, New Frontiers in Research Fund, and Instituto Nazionale per l'assicurazione contro infortune sul lavoro. He received educational funds from Medtronics of Canada Ltd, and is the chairholder of Medtronic Research Chair in Spinal Trauma at Université de Montréal. He is co-founder, shareholder and board member of Spinologics Inc. and subsidaries. He received salary support from Fonds de recherche du Québec – Santé.

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Received: 6 February 2026 / Accepted: 3 April 2026
Published online: 07 April 2026

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