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The Effect of Body-Weight Support Treadmill Training on Gait Speed for Patients with Incomplete Spinal Cord Injury

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Clinical Scenario: The patient who led me to pursue this question is a 52-year-old male, approximately 28 months post-incomplete spinal cord injury (iSCI) at T11. Medical treatment to date has included over-ground gait training, strength training, and functional activities. Physical therapy diagnoses include gait abnormality and general weakness.

Brief Introduction: For the purposes of my clinical question, I want to determine the effectiveness of body weight support treadmill training for walking speed for patients with incomplete spinal cord injury. The patients I am working with at Oregon Health and Science University (outpatient) often present with deficits in gait, balance, strength, flexibility and/or cognition.

My Clinical Question: Is body-weight support treadmill training an effective intervention for increasing gait speed for patients with incomplete spinal cord injury?

Clinical Question PICO:

Population – 52 yo male, 28 months post iSCI at T11 level
Intervention – Body weight support treadmill training (BWSTT)
Comparison – Over-ground training
Outcome – Walking speed

Overall Clinical Bottom Line: Based on the results from Dobkin et al. and Hicks et al., BWSTT has the potential to increase walking speed in patients with both acute or chronic iSCI and classified as ASIA C or D. According to Dobkin et al., patients with acute iSCI (<8 weeks post-iSCI) can benefit equally from BWSTT or over-ground gait training 5x/week for 12 weeks to improve and maintain walking speed for up to 3-months. According to Hicks et al., patients with chronic iSCI (≥12 months post-iSCI) can improve and maintain walking speed for up to 8-months after BWSTT 3x/week for 144 sessions. Since these given treatment frequencies and durations are likely unreasonable for an average person and BWSTT systems are expensive, it may be best to utilize BWSTT (if it is readily available for use) until the patient is able to walk over-ground. Once over-ground gait training is possible, this can be practiced and maintained as a home program and challenged and progressed at therapy.

Search Terms: Spinal cord injury, treadmill, body-weight support, rehabilitation

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Rationale for Articles:
I found my articles through the Medline and PubMed databases. I decided on these three articles out of the few I was able to find, as they were the most current to date and pertained to my key components of body weight support treadmill training and patients with incomplete spinal cord injury. As shown below, these articles match my patient's age, contain subjects with incomplete spinal cord injuries, and examine the effect of body-weight support treadmill training on gait speed post-treatment and at a follow-up.

1) Dobkin B, Apple D, Barbeau H, et al. Weight-support treadmill vs over-ground training for walking after acute incomplete SCI. *Neurology* 2006; 484-493.

PEDro Score = 7/10
P = aged 16-70 y/o, SCI within 56 days, incomplete lesion below C4 unilateral & above L3 bilateral, ambulate over-ground with at least mod A, MMSE>=26
I = Weight-support treadmill training
C = Over-ground walking,
O = Walking speed for ASIA C and D, 6 month follow-up

2) Hicks AL, Adams MM, Ginis KM, et al. Long-term body-weight-supported treadmill training and subsequent follow-up in persons with chronic SCI: effects on functional walking ability and measures of subjective well-being. *Spinal Cord* 2005; 291-298.

PEDro Score = 3/10
P = aged 20-57 y/o, post-acute phase of rehab, ASIA B and C
I = Body-weight support treadmill training
C = Pre-body-weight support treadmill training
O = Walking speed, subjective well-being, 8-month follow-up

3) Musselman KE, Fouad K, Misiaszek JE, et al. Training of walking skills overground and on the treadmill: case series on individuals with incomplete spinal cord injury. *Physical Therapy* 2009; 601-611.

PEDro Score = 3/10
P = >=10 yrs post, walk 5m overground with or with AD or assist, age 24-61, C5-L1
I = Treadmill
C = Overground
O = Walking speed, 3-month follow-up

	Dobkin et al.	Hicks et al.	Musselman et al.
Random	1	1	1
Concealed Allocation	0	0	0
Baseline Comparability	1	0	0
Blind Subjects	0	0	0
Blind Therapists	0	0	0
Blind Assessors	1	0	1
Adequate Follow-Up	1	1	0
Intention-to-Treat	1	0	0
Between Group	1	0	0
Point Estimates & Variability	1	1	1

TOTAL SCORE (* PEDro database)	7/10 *	3/10	3/10

Based on the above comparisons, I have chosen to write this critically appraised paper on the articles by Dobkin et al. and Hicks et al. The Dobkin et al. article has a high PEDro score while the Hicks et al. article has a more similar post-iSCI time period to my patient and a longer follow-up period.

Article: Dobkin B, Apple D, Barbeau H, et al. Weight-support treadmill vs over-ground training for walking after acute incomplete SCI. *Neurology* 2006; 484-493.

Clinical Bottom Line: Based on this article, BWSTT 5x/week for 12 weeks is equally as beneficial as CONT for improving walking speed and maintaining this improvement at a 3-month follow-up for patients < 8 weeks post-iSCI with ASIA C or D classification. With the high cost and limited availability of BWSTT, it may be more reasonable to provide CONT to improve gait for these patients if they are able to devote this much time to therapy.

Article PICO:

Population – 68 subjects (age range = 17-69 y/o) with onset of iSCI < 8 weeks ago and classified upon admission as ASIA C or D
Intervention – 12 weeks of BWSTT
Comparison – 12 weeks of over-ground mobility training (CONT)
Outcomes – Walking speed (m/s)

Blinding: The assessors who conducted the outcome measures were blinded. The lack of subject and therapist blinding does not pose a significant threat to the results of this study.

Controls: There was no true control group in this study. Instead, they compared the effects of BWSTT vs. CONT. Since it is unethical to have a true control group, over-ground gait training is an appropriate comparison because anyone can practice walking over-ground.

Randomization: Subjects were randomized into their given treatment groups through a random, permuted block design. This randomization method was successful as subject characteristics (age, days post-injury, spinal level, walking speed) were similar across groups at baseline.

Study:
The purpose of this single-blinded, randomized clinical trial was to compare the effects of BWSTT vs. CONT for subjects with acute iSCI. The 68 subjects (age range = 17-69 y/o) were recruited through screening of all admissions to six SCI units during June 2000 to January 2003. All participants experienced an iSCI < 8 weeks prior to this study and classified as ASIA C or D. Exclusion criteria consisted of the following: symptomatic orthostatic hypotension or > 30-mmHg drop when upright in the BWS apparatus, spine-stabilizing device, contraindication to weight bearing on lower extremities, pressure sore ≥ stage 2 located where the harness or treadmill training could affect healing, debilitating disease prior to SCI that cause exercise intolerance, require anti-spasticity medication, premorbid major depression or psychosis, unlikely to complete intervention or return for follow-up, and participation in another research

study. All subjects received standard inpatient and outpatient rehabilitation for mobility and ADLs, but their main component of mobility training consisted of BWSTT or CONT 5x/week for 12 weeks (3 months). Both groups performed gait training for up to 1 hour/day, depending on each individual's exercise tolerance, and stretching exercises for up to 10 mins/day. The BWSTT group engaged in gait training using BWS for 20-30 mins in 3-10 min intervals, with individualized treadmill speed and %BWS that allowed the subject to train at speeds between 0.72-1.07 m/s. Once over-ground walking was possible, this was practiced for an additional 10-20 mins/day. Therapists provided assist for trunk and lower extremity kinematics, limb loading, and proprioceptive feedback during reciprocal stepping. The CONT group performed a minimum of 30 mins of standing for subjects who could not ambulate, and 30-45 mins of walking in parallel bars or over-ground with assistive devices, braces, or assistance from 1-2 therapists for those who could ambulate. Throughout this study, participants in the CONT could not use a treadmill or BWS, but both groups could perform leg and trunk strengthening exercises. Gait training could be stopped when subjects achieved a walking speed of 0.98 m/s. Upon completion of the study, participants were able to receive conventional outpatient therapy if recommended by their physician.

Outcome measures:
Trained, blinded assessors obtained measures of over-ground walking speed at baseline, and at 3-, 6-, and 12-months. The authors did not report validity, intra-/inter-rater reliability, or MCIDs, but walking speed can be considered a "gold" standard.

Study losses:
The number of study losses and reasons for losses were not clearly stated in the article. However, there was adequate follow-up as presented by the PEDro database score.

Summary of internal validity:
Threats to internal validity include lack of blinding of subjects and therapists and no true control group. While these could pose as threats, I do not believe they significantly affect the results of this study since the assessors, who are more prone to bias, were blinded, and they compared BWSTT vs. over-ground training.

Evidence:
At the start of the study, no one in the BWSTT group was able to ambulate, while 2 subjects in the CONT group were able to ambulate at 0.2 m/s and 0.4 m/s. At the 3-month follow-up, both the BWSTT and CONT groups were able to walk at a median speed of 1.1 m/s and 1.0 m/s, respectively. Although they both improved, there was no difference between the two treatment groups ($p = 0.65$).

Table 1. Walking speed outcomes at baseline and 3-month follow-up between BWSTT and CONT groups

	Baseline	6 months (3-month follow-up)
BWSTT	0	1.1 (0.8-1.4) m/s[#]
CONT	(n=2) 0.2 m/s and 0.4 m/s	1.0 (0.7-1.5) m/s[#]
	N/A	P = 0.65

[#] *Walking speed values given as medians (interquartile range)*

Applicability of study results:
Benefits vs. Costs: BWSTT can be costly and access to such equipment is very limited. As shown by the results of this study, both BWSTT or CONT for 5x/week for 12 weeks can be equally beneficial for improvements in walking speed for patients with acute iSCI (ASIA C or D). Therefore, due to the costs and limitations of BWSTT, it may be more reasonable to perform CONT with these patients.

Feasibility of treatment: As stated above, BWSTT is very costly and only a few clinics have such equipment. Based on patients' insurance, transportation, and time, 5x/week for 12 weeks is likely not a reasonable treatment frequency and duration.

Summary of external validity: The subject population of this study is similar to that of the patients we are likely to see in the clinic, especially being <8 weeks post-iSCI. While there are threats to internal validity, they are not significant enough to keep me from extrapolating these results to the larger patient population with iSCI, specifically those classified as ASIA C or D.

Article: Hicks AL, Adams MM, Ginis KM, et al. Long-term body-weight-supported treadmill training and subsequent follow-up in persons with chronic SCI: effects on functional walking ability and measures of subjective well-being. *Spinal Cord* 2005; 291-298.

Clinical Bottom Line: Based on this article, BWSTT 3x/week for 144 sessions has the potential to increase walking speed and the modified Wernig scale score, and decrease %BWS, for individuals with chronic iSCI classified as ASIA C or D. Subjects who did progress to independent walking from baseline to post-BWSTT were able to maintain their increased walking speed, but required more %BWS at the 8-month follow-up. Overall, there is potential for improvement for patients with iSCI and ASIA C or D classifications, but BWSTT is costly and patients may not have the time to devote to 3x/week locomotive training.

Article PICO:

Population – 14 subjects with chronic (mean = 7.4 yrs post-injury) iSCI, classified as ASIA B or C, and wheelchair-dependent at onset of study
Intervention – BWSTT for 3x/week over 12 months
Comparison – Pre-BWSTT
Outcomes – Functional walking ability (walking speed, %BWS, modified Wernig scale)

Blinding: The lack of blinding in this study, especially that of the assessors, could pose a threat to the outcomes presented.

Controls: This was a within-subject study design and therefore, no true control group due to the high potential for drop-out of and ethical implications for those participants assigned to a control group. While this lack of a control could interfere with the validity of the results, it is believed that these subjects were unlikely to experience spontaneous improvement being 7.4 years post-injury on average.

Randomization: Since this was a within-study design, randomization was not necessary as subjects are compared across their own pre- and post-test measures.

Study:
The purpose of this study was to discover the effects of BWSTT 3x/week over 12 months on gait speed. The 14 subjects (age range = 20-53 y/o; 11 males, 3 females) were recuited through the Central West Ontario Regional SCI Rehabilitation Program at Chedoke Hospital in Hamilton and local advertisements. All participants suffered a traumatic iSCI ≥12 months prior to this study (lesion range = C4-L1) and were classified as ASIA B (2) and C (12). Exclusion criteria consisted of the following: cardiac pacemaker, unstable angina or documented heart disease, uncontrolled cardiac dysrhythmia, chronic obstructive lung disease, uncontrolled autonomic dysreflexia, recent non-traumatic fracture, tracheostomy, B hip and knee flexion contractures >20°, drug addiction, age >60 yrs or persons >40 yrs who failed phase I of a progressive incremental exercise tolerance test, and severe muscle shortening or severe skin ulcerations. All subjects trained on the Woodway Loco-system treadmill 3x/week for a total of 144 sessions, with a minimum of two therapists assisting with gait during 3 bouts of walking per each session. On day 1, an appropriate BWS level was determined for each subject, providing just enough support so they could maintain an upright trunk and not have their knees buckle. Initial treadmill speed was based on patient tolerance and safety and both treadmill speed and %BWS was modified respectively across the duration of the study. Upon completion of the BWSTT study, subjects were offered optional weekly BWSTT and/or bi-weekly fitness training (arm ergometry and resistance training), and a follow-up assessment was conducted at 8-months post-study.

Outcome measures:
Functional walking ability was the main outcome measure I was interested in examining. This included measures of walking speed, %BWS provided during typical BWSTT session, and over-ground walking ability via the modified Wernig scale. Walking speed and %BWS data was gathered every 36 sessions (3 months) up until 144 sessions (12-15 months) and an 8-month follow-up, while the modified Wernig scale was assessed at baseline, post-BWSTT, and an 8-month follow-up. The authors did not report validity, intra-/inter-rater reliability, or MCIDs for these measures, although walking speed and % BWS can be considered a "gold" standard.

Study losses:
One participant was lost after 6 months of training due to lack of compliance and another did not return for the 8-month follow-up. No specific reasons were provided for these loses. No intention-to-treat analysis was performed.

Summary of internal validity:
Threats to internal validity include lack of blinding, a true control group, and reports of validity for functional walking ability measures. I believe the lack of blinding and evidence of validity for the modified Wernig scale have the most significant impact on the internal validity. Without blinding, especially that of the assessors, the results of the study could have easily been biased when measuring outcomes. The modified Wernig scale seems logical and valid but without any evidence of that or MCID, this cannot be certain. Since these subjects were on average 7.4 years post-injury, the lack of a true control group does not seem too detrimental to the results. In addition, the lack of evidence for measures of treadmill speed and %BWS seem minimally harmful since these improvements could be relative to over-ground gait speed and amount of support needed during over-ground walking.

Evidence:
Following the 3x/week BWSTT over 144 sessions, all subjects made significant improvements in their functional walking ability as evident by increases in walking speed and decreases in %BWS. In fact, 4 subjects were able to walk on the treadmill without BWS at the end of training. However, %BWS increased at the 8-month follow-up as compared to the post-BWSTT measure, but still remained significantly better than the baseline measure. Walking speed stayed the same at the 8-month follow-up as compared to the post-BWSTT measure.

Table 1. Walking speed and %BWS measures at pre-training, post-training, and follow-up

	Baseline	Post-BWSTT	8-month Follow-up
Walking speed (m/s)	0.14 ± 0.08 m/s	0.39 ± 0.22 m/s*	0.39 ± 0.22 m/s*
%BWS	73.1 ± 10.3%	19.5 ± 12.2%*	34.9 ± 14.4%*$^{+}$

* *P<0.01 when compared to baseline measure*
$^{+}$ *P<0.01 when compared to post-BWSTT*

The modified Wernig scale is an objective measure of over-ground walking ability (Table 2). At baseline, only three subjects had scores > 0. After training, there was six subjects with scores > 0, including one participant who could walk > 5 steps without any assistive device. There were no changes in mean scores between the 8-month follow-up and post-BWSTT (Table 3).

Table 2. Over-ground walking ability as scored via the modified Wernig scale

Score	Classification
0	No walking capability, even with help of two thrapists
1	Capable of walking < 5 steps with the help of two therapists OR along parallel bars
2	Capable of walking ≥ 5 steps with the help of two therapists OR along parallel bars
3	Capable of walking > 1 length of the parallel bars, requiring assistance to turn
4	Capable of walking > 1 length of the parallel bars, turning independently
5	Capable of walking along railing (< 5 steps) with the help of one therapist
6	Capable of walking along railing (> 5 steps) with the help of one therapist
7	Capable of walking with a rolling walking frame > 5 steps
8	Capable of walking with canes or crutches > 5 steps
9	Capable of walking without devices > 5 steps

Table 3. Modified Wernig scale scores at pre-training, post-training, and follow-up

Participant	Baseline	Post-BWSTT	8-month Follow-up
1	8	9	8
2	0	7	7
3	4	6	N/A
4	0	0	0
5	0	4	4
6	7	7	7
7	0	0	0
8	0	0	0
9	0	2	0
10	0	0	0

11	0	0	0
12	0	0	0
13	0	0	0

Only 13 of the 14 subjects are listed in this table because one was unable to remain compliant with the 3x/week training sessions. Participant 3 has no follow-up score since they did not return for reassessment.

Applicability of study results:

Benefits vs. Costs: BWSTT can be costly and access to such equipment is very limited. As shown by the results of this study, BWSTT has the potential to improve functional walking ability after 3x/week training over 12-15 months. However, maintenance of these improvements only seem probable for participants who progress to fully unloaded walking abilities as they are able to put their gains to use outside of therapy or discharge.

Feasibility of treatment: As stated above, BWSTT is very costly and only a few clinics have such equipment. Based on patients' insurance, response to treatment, transportation, and time, 3x/week for a total of 144 sessions may not be reasonable for many. If anything, BWSTT has the most potential for improvement and maintenance of improvement for patients classified as ASIA C or D, as they are more likely to progress to independent ambulation.

Summary of external validity: The subject population of this study is similar to that of the patients we are likely to see in the clinic. While there are threats to internal validity, I do not think they are so detrimental that we cannot extrapolate these results to the larger patient population with iSCI, specifically those classified as ASIA C or D.

Synthesis/Discussion:

Based on the results by Dobkin et al. and Hicks et al., patients with acute or chronic iSCI (ASIA C or D) can improve their walking ability and walking speed and maintain these gains for up to 3 months (acute) and 8 months (chronic). However, clinical applicability of these methods to produce these given outcomes is fair at best, due to the following:

The PEDro score is a way to rank the methodological quality of articles related to treatment. The Dobkin et al. article has a fairly high PEDro score of 7/10, while the Hicks et al. article is ranked poorly at a 3/10. One of the major problems with the Hicks et al. study is the lack of blinding, especially that of the assessors, which leaves open the possibility of bias. Even more so, since both studies lacked a true control group due to ethical implications, it is impossible to know whether the improvements and maintenance in walking speed are exclusively due to the use of BWSTT or just the high frequency and duration of being physically active.

Between these two studies, BWSTT treatment variables differed by frequency, duration, speed, and therapist assistance. Subjects in the Dobkin et al. study received BWSTT 5x/week for a total of 12 weeks. At each session, participants were stretched for 10 mins and performed 20-30 mins of supported treadmill walking at speeds between 0.72-1.07 m/s as tolerated. Once over-ground walking was possible, subjects would practice this for 10-20 mins/session. Participants in the Hicks et al. study took part in BWSTT 3x/week for a total of 144 sessions. The %BWS provided for each individual was determined by their ability to maintain an upright trunk and limit knee buckling, while treadmill speed was increased as able. In addition, at least 2 physical therapists provided hands-on assist for proper gait mechanics at each session.