**PICO question: For patients with moderate to severe traumatic brain injury under the age of 40 and without previous neurological occurrence, is over-ground manually-assisted gait training and handrail support or a body weight-supported device more beneficial for improving functional abilities as measured by over-ground walking speeds?**

**Introduction:**

Traumatic brain injury (TBI) is the leading cause of death and impairment in young adults in America1. Injury leading to TBI occurs in 1.5 to 2 million people every year. 50,000 of these people die and over 230,000 survive with hospitalization and extensive rehabilitation. Of those that survive, approximately 90,000 will live with lifelong intellectual, behavioral, and/or physical disabilities that will limit their ability for functional independence in their home and community. Motor vehicle accidents are the most common cause of TBI with falls, violence, and sports being responsible for the majority of the others. Men are more often victims than females and young adults aged 15-24 are more at risk than others1. The level of severity after injury is determined by the patient’s level of consciousness, score on the Glasgow Coma Scale, and the duration of post-traumatic amnesia. The severity of injury is one of the most reliable predictors of outcome2,3.

TBI is difficult to both treat and compare research because of its effects on multiple body systems and its heterogenic presentations between individuals lending itself to a paucity of research regarding clinical practice guidelines4. One of the most visible deficits after TBI is motor impairment and movement dysfunction. This is often caused by upper motor neuron syndrome (UMNS) which causes spasticity, decreased reflexes in the lower extremities, loss of dexterity, and weakness. UMNS can have significant effects on one’s ability to perform functional activities. Though presentations are varied, patients commonly demonstrate deficits in force, endurance, coordination and balance5. These impairments negatively affect one’s ability for ambulation which is directly correlated with decreased independence and quality of life10. Two common gait training mechanisms in the clinic are conventional over-ground gait training (COGT) and body weight-supported treadmill training (BWSTT). COGT consists of a physical therapist observing, giving verbal and tactile cues, and physical assistance as needed while the patient ambulates over a regular floor surface. This can also include separate exercises that are aimed at improving overall locomotor function6. BWSTT involves use of a body weight-support device that elevates the patient using a harness system while maintaining foot contact with the treadmill11. The literature is clear that COGT is necessary for ideal recovery of those with an acute injury and an inability to walk independently7. Recently, however, the use of BWSTT has increased in the clinic and clinicians have begun researching the efficacy of this treatment approach in comparison to COGT.

After central pattern generators were discovered through the work of Grillner with spinalized cats walking on a treadmill, ideas for gait training for patients with injury to their CNS began to develop8. Barbeau and Rossignol found that these spinalized cats could demonstrate improved quality of locomotion if they were given a locomotor training program in which the researcher gradually decreases the body weight-support while increasing the velocity of the treadmill9. If this is true for a cat, perhaps a similar response would occur in humans with similar injuries. Research into this topic for patients with traumatic brain injury is lacking in quality evidence. The evidence is varied regarding whether BWSTT or COGT is more effective. Greater evidence exists for other neurologic conditions such as Stroke, Parkinson’s Disease (PD) and Cerebral Palsy. Patients with each of these diagnoses show improvements in gait velocity and stride length after BWSTT as compared to COGT11.

**Objectives:**

The purpose of this paper is to conduct a comprehensive review of the literature to evaluate the efficacy of BWSTT versus COGT. Results were based on multi-dimensional outcome measures of gait function and performance measures such as gait speed and step width. Clinicians will be able to use the conclusions of this review to determine the most beneficial type of treatment. It will also benefit rehabilitation mangers by giving justification of purchase of a body weight-supported device.

**Methods:**

Outcome measurements: The primary outcome measures used in the studies being reviewed were the Functional Ambulatory Category (FAC)1,2,3,4,5,7, the Standing Balance Scale (SBS)2,3,5, the Rivermead Mobility Index (RMI)3,4, Modified Ashworth Spasticity Scale (MASS)2,4, and the Functional Independence Measure (FIM)3. The performance measures used were gait velocity1,4,6,8, step width1, step length8, and displacement of center of mass (COM)6. Each of these outcome measures were chosen based on their relevance to the population and the intended benefits of the gait training treatment. The FAC is a quick (1 minute) test that involves observation of a patient’s ability to walk followed by a score of 1-5. It has excellent test-retest reliability (κ= 0.950) and excellent interrater and intrarater reliability (κ = 0.905); however, this is based on evaluation of stroke patients. Stroke patients have a similar injury, but further testing is required to know the applicability of the FAC for patients with TBI19. Similarly, the RMI is a measure created for stroke patients that uses a graded scoring system to determine motor performance via 15 self-reported questions that are quantified by yes (1) or no (0). It has excellent interrater reliability (ICC=0.92)19. The SBS assesses one’s ability to stand upright and uses a 5-point likert scale to score unable to stand (0) to able to stand with feet together for greater than 30 seconds (4)13. This scale has not been tested for psychometric properties. The FIM is a very commonly used measure in rehabilitation facilities that consists of 18 items (13 motor; 5 cognitive tasks) rated on a 7 point ordinal scale where a higher number indicates increased independence. This is the only measure that has been tested for use with victims of brain injury and has excellent test-retest reliability for this population. (ICC= 0.85 for total FIM, 0.92 for motor FIM, and 0.69 for cognitive FIM)19.

Study design: Randomized control trials (RCT) are the gold standard research design; however, they are difficult to implement in this population because of the small number of patients per facility as well as the ethical dilemma of obtaining appropriate consent from an individual with significant cognitive deficits. Furthermore, the time necessary for treatment to take its full effect is often months or even years and many large experimental design studies are unable to receive funding for that period of time. RCTs are therefore uncommon in the literature for gait training for patients with TBI. There are currently two RCT studies researching the question at hand; however, both have small sample sizes, decreasing their clinical effect size. Because RCTs are sparse, it is important to take note of the observational and nonrandomized designed studies in order to obtain the clearest picture of the available evidence. The majority of other studies are case studies, quasi experimental designs, cohort studies, and single system designs.

**Results:**

 The general consensus from the literature is that BWSTT is equally as effective as COGT, but is not superior in regards to functional gait outcomes such as gait speed. Brown and colleagues were the first to provide a RCT studying the difference between outcomes for BWSTT verses COGT for patients with TBI. A total of 20 participants received gait training for 14 weeks total, 2 times per week for 15 minutes with an additional 30 minutes of therapeutic exercise. A LiteGait device was used to unweight the subjects starting at 30% body weight support, decreasing by 10% each time the patient was able to obtain 10 consecutive heel strikes. The only statistically significant difference was an improved right-left step differential in the BWSTT group. Though not statistically significant, the COGT group improved slightly more than the BWSTT group on other measures such as the FAC, TUG, and gait speed11. Similarly, Wilson and Powell completed an RCT three years later with the same intentions. They had an increased sample size (38 participants) and increased treatment time each session (one hour or less twice per week). They used the Pneu-Weight device and decreased body weight as the patient felt comfortable. All of the subjects showed improvements in all outcome measures; however, there was no statistical significance between groups for any of the measures. Scores were higher for the COGT group on the FAC. Scores were higher for the BWSTT group on the SBS, RMI, and FIM13.

 A few studies looked at the use of BWSTT for specific types of patients with TBI. Wilson studied this treatment’s effect on patients with acute TBI versus chronic TBI12. Clark et al performed a cohort study exploring BWSTT’s effect on the change in center of mass during gait in patients with an acquired brain injury16. Freund and colleagues researched how the BWSTT treatment would affect a patient with TBI presenting with severe cerebellar ataxia17. These approaches allow clinicians to apply treatment findings to a more narrowed patient type. Wilson found that both patients showed improvements over the 8 week treatment period, but the patient with acute injury improved more than the patient with chronic injury12. Clark’s results indicated that those subjects who received BWSTT without a therapist’s assistance and without upper extremity (UE) support had the greatest amount of displacement of their COM which decreased their timing and stability. The method that showed the most gait similarities to that of a non-pathological patient was the BWSTT group with therapist assistance and UE support, showing a statistically significant difference between the groups in decreased COM displacement and improved timing and stability16. Freund found that the patient with cerebellar ataxia made significant improvements from the 6 week testing period to the 10 week testing period on the Berg Balance Scale (BBS), 10-Meter Walk Test (10-MWT), FAC, the confidence portion of the OPTIMAL, and the Trunk endurance test. This demonstrated that a patient with TBI and severe ataxia may benefit from a combined intervention of BWSTT plus trunk stabilization exercises to improve gait and balance17.

 The remaining studies looked at the effect of BWSTT on other neurological diagnoses similar to TBI. Hesse et al compared results of COGT versus BWSTT for seven stroke patients14. Scherer examined the effects of BWSTT on a patient post blast injury in the Iraqui War15. Fritz and colleagues studied the effectiveness of BWSTT for four patients each with a different neurological diagnosis18. Hesse found that after 9 weeks of BWSTT treatment, patients showed statistically significant improvements on the FAC and gait velocity as compared to the COGT group. Prior to the study, most of the patients required constant support from one or two therapists for ambulation. Post BWSTT, three of the subjects were walking independently and only required assistance during stair climbing. Three of the other subjects only required verbal cueing and supervision for gait14. Scherer followed a soldier post blast injury for 11 weeks of BWSTT. His scores on maximum distance ambulated improved by 275%. He improved from being non-ambulatory to walking 133 feet with minimum assistance15. Fritz studied the use of BWSTT for four patients with incomplete spinal cord injury (ISCI), Parkinson’s Disease (PD), Stroke (CVA) and cerebral hemispherectomy (HEMI). All patients showed improvements in step velocity except for the patient with ISCI. The two patients with ISCI and PD required more rest breaks than the other two. The patient with HEMI showed the greatest improvement on the 6-minute walk test (6MWT)18.

**Discussion:**

The literature does not give significant evidence to show that BWSTT is superior to COGT for patients with TBI; however, there were many clinical implications for those using BWSTT in practice. Results indicate that BWSTT is more useful for patients with acute injuries as opposed to chronic injuries12, can be beneficial for patients with cerebellar ataxia17, and is most effective when the patient is given assistance by the physical therapist as well as UE support16. Most studies conclude that both groups showed improvement but not one group more significantly than the other11,13. Half of the studies had both groups participating in additional physical therapy which reduces the probability that the increased functional outcomes were a product of gait training alone1,2,3,7. Further research is required to make any definite conclusions about the effectiveness of BWSTT. Outside of gait related outcomes, BWSTT has multiple significant benefits such as decreasing the physical stress on the therapist, increasing safety for the patient, allowing specific task practice, and is both physiologically and psychologically beneficial for the patient and their families11,20.

Various limitations exist in the studies outlined such as bias, lack of randomization, small sample size, and low power. Sample size is a common limitation in each of the studies with total sample sizes ranging from 1 to 38. The largest sample size used was in the Wilson study, which was the same article that calculated a need for a sample size of 5,000 subjects in order to maintain a power of 80% and an alpha level of 0.0513. The extent to which this study was underpowered due to the small sample size shines light on the limitations of the other studies with even smaller sample sizes. Bias was also a common limitation among the studies. Only two studies used subjects chosen at random11,13; the others chose subjects based on convenience or self-selection indicating selection bias. Measurement bias was also a factor for those studies that used outcome measures that had not yet been tested for psychometric properties such as the SBS and Missouri Assisted Gait Scale12,13,15 and those who have not been tested for use in the TBI population such as the FAC and RMI11,12,13,14,15,17. Furthermore, neither the patient nor the therapist was blinded in any of the studies. For the studies that gave details about testing, the investigator and the assessor were one in the same, indicating possible tester bias. It is inevitable for the patient and investigator to realize their treatment group; however, assessors should be blinded to which patients are receiving what treatment and should be separate from the investigator to ensure no influence of extra knowledge. External validity was affected in studies in which the subjects were dissimilar to one another such as in the Wilson12 and Fritz studies18. These studies would benefit from increased homogeneity of subject presentation.

Several of the studies failed to provide a standardization regarding when to increase speed on the treadmill and only two studies explained how and when they would reduce the percentage of body weight support. Some even stated that this was a subjective decision by the therapist. This lack of standardization could introduce bias into the study and affect results. Many of the results were poorly represented. In the Wilson study, initial values for pre-treatment spasticity, strength, and outcome measures were absent. In the Hesse study, the authors did not present any of the statistical analysis values in terms of P values or ICC values. Lastly, the lack of effort to control for extraneous variables such as additional rehab treatments, tone and spasticity, cognitive function, family support, and length of treatment decreases the value of the studies for use in determining effect of BWSTT on outcomes in patients with TBI. Decreased controls limit one’s confidence that results are due to the treatment alone and not a result of chance or spontaneous recovery.

**Conclusion:**

 Traumatic brain injury is a devastating diagnosis that is largely variable in its presentation and recovery time. Clinicians can benefit patients and families by being well educated in the current literature regarding best practices for treatment. Specifically, knowing options for gait training and the most effective techniques and devices may improve functional outcomes for the patient, increasing their independence in the most time efficient way. Furthermore, rehab managers will benefit from knowing evidence based benefits of a body weight-support device to decide if the benefits of the purchase outweigh the costs. One way to provide this education to clinicians and rehab managers is through a Capstone project case study and presentation at a local hospital with a TBI patient population. Continued research is indicated to compare gait related outcomes between BWSTT versus COGT for patients with moderate to severe traumatic brain injury. Future studies would benefit from providing a randomized, large sample that is exposed to a controlled environment and has blinded outcome assessors.

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