

2010

The effects of body weight support treadmill walking for older adults with lumbar spinal stenosis compared to standard back stabilization exercises

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Recommended Citation

Jakubowski, Ali, "The effects of body weight support treadmill walking for older adults with lumbar spinal stenosis compared to standard back stabilization exercises" (2010). *PT Critically Appraised Topics*. Paper 14.
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The effects of body weight support treadmill walking for older adults with lumbar spinal stenosis compared to standard back stabilization exercises

Disciplines

Physical Therapy

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CRITICALLY APPRAISED TOPIC

Title: The effects of body weight support treadmill walking for older adults with lumbar spinal stenosis compared to standard back stabilization exercises.

Overall Clinical Bottom Line:

I evaluated two articles written between the years of 2006 and 2007 that assessed the use of body weight support treadmill training (BWSTT) with adults with lumbar spinal stenosis (LSS). These studies did not support the use of BWSTT in treating adults who are not good candidates for surgery to correct LSS. The articles by Whitman *et al.* and Pua *et al.* are not very good matches to my clinical question, though they were of excellent quality (both ranking 8/10 on the PEDro scale). The Whitman *et al.* article was a randomized controlled trial with 58 older adults with LSS comparing manual physical therapy, flexion exercises and BWSTT to flexion exercises, sub-therapeutic ultrasound, and treadmill walking. Pua *et al.* used a randomized controlled trial design with 68 older adults with LSS and compared BWSTT to cycling in conjunction with an exercise program and mechanical lumbar traction. The results of these articles show no statistically significant difference between interventions over 6 weeks. The effect size between groups (95% CI) according to the Whitman *et al.* and Pua *et al.* studies are 0.29 (-0.23 – 0.8) and 0.19 (-0.29 – 0.66) respectively; indicating a very small change that either intervention would have reduced pain or improved functional capabilities for subjects. The overlap or going below zero of the 95% CI signifies subjects could have gotten worse with treatment. For improvements in functional capabilities, the NNT according to the Pua *et al.* article was 45 (-4.8 – 3.9). Both of these articles had adequate internal validity. Based on the evidence, I would not incorporate BWSTT in my treatment program as an intervention for older adults with LSS. There is no statistical significance for either study, thus further research is needed in order to accept any potential results. These articles would not affect my treatment interventions for older adults with LSS who do not qualify for surgery.

Clinical Scenario: I am currently working with an older adult who has severe spondylosis as well as spinal stenosis of her lumbar and cervical spine. This patient is not a good candidate for spinal surgery due to her other health conditions. Therefore, I was interested in finding a non-surgical intervention incorporating activities she enjoys; such as walking. I wanted to know if BWSTT would give the same results as back stabilization exercises. I would like to determine whether using BWSTT as a critical component within a comprehensive treatment program for spinal stenosis is beneficial. For many older adults their main form of physical activity is walking. Therefore, I wanted to find an intervention that implemented activities older adults would be familiar with to encourage compliance.

Clinical Question:

Population— Adults with spinal stenosis

Intervention – BWSTT

Comparison – Back stabilization exercises without BWSTT

Outcome – Pain rating scale and functional index survey

Search Terms: spinal stenosis, spondylitis, ankylosing spondylitis, therapeutic exercise, treadmill walking, low back pain

Appraised By: Ali Jakubowski SPT on September 23, 2010

Introduction

Spinal stenosis is a narrowing of one or more areas in the spine, most often in the neck or lower back. Narrowing can put pressure on the spinal cord or spinal nerves at the level of compression. Spinal stenosis is commonly caused by age related changes in the spine, most common among the elderly population (Zarife, et al 2009). Low back pain (LBP) has an enormous effect on health care utilization and cost (Joffe et al, 2002).

Symptoms associated with spinal stenosis are: bilateral low back, buttocks, thighs, calves, and foot pain. Pain decreases with spinal flexion and sitting. Pain increases with spinal extension, prolonged walking and standing. Active and passive ranges of motion are restricted. Patients may have a positive single leg raise and describe having numbness and burning in lower extremities. (Magee, 2002).

Spinal stenosis can be difficult to diagnose because of its signs and symptoms, which resemble those of many age related conditions. Tests may be needed to help identify the true causes of signs and symptoms. Magnetic resonance imaging is the most commonly used tool for diagnosing spinal stenosis. The images may show damage to discs, ligaments, and as well as where pressure may be on the spinal cord or spinal nerves (Mayo clinic website, 2010).

Currently the main treatment for spinal stenosis is surgery to create additional space for the spinal cord and nerves (Mayo clinic website, 2010). Due to high morbidity and mortality rates associated with surgical interventions for patients in this population, research is being done to look at non-surgical alternatives for older adults with LSS (Ragab et al, 2003).

Many of the aggravating activities are due to increased axial loading on the spine, such as standing and walking and are relieved by rest, particularly lying down which unloads the spine. Lumbar traction is a frequently used intervention for LSS. Traction is thought to cause flattening of the lumbar lordosis, with distraction of the vertebral bodies and an increase in disc height, stretching of spinal ligaments and muscles, widening of intervertebral foramina, and separation of the facets.

Use of a partial body weight support (PBWS) system during walking allows for traction components during a functional activity. The traction is intended to reduce the compressive forces on the spine during ambulation and decrease the pain. (Joffe et al, 2002). Exercise regimens have also shown to give short and long term results; focusing on specific strengthening and flexibility exercises for shortened muscle chains (Fernandez de las et al, 2006).

Therefore, the purpose of this paper is to compare a functional intervention, such as body weight support treadmill walking to a back stabilization exercise program for older adults.

Article # 1: Whitman, J., Flynn, T., Childs, J., Wainner, R., Gill, H., Ryder, M., Garber, M., Bennett, A., Fritz, J. (2006). A comparison between two physical therapy treatment programs for patients with lumbar spinal stenosis. *SPINE*. 32 (22) 2541-2549.

Clinical Bottom Line: Based on the results of this study, there is weak evidence to suggest that adults older than 65 with lumbar spinal stenosis (LSS), have a better outcome with an intervention of manual physical therapy, flexion exercises and body weighted supported treadmill training (BWSTT) than with flexion exercises, sub-therapeutic ultrasound, and treadmill walking program. The effect size (95% CI) between groups at 6 weeks for the OWS and Numerical Pain Rating Scale (NPRS) for average thigh/leg pain is 0.15 (-0.36 – 0.67) and 0.17(-0.34 – 0.69) respectively, indicating a small effect size, meaning neither treatment made a significant change in symptoms. The 95% CI at 6 weeks for both outcome measures crossed zero, signifying that subjects could have gotten worse by either intervention. The study had adequate internal validity due to successful randomization into groups, no dropouts and subject compliance. My primary concern is this article does not directly address my clinical question. In this study the “intervention group” (MPTE_xWG) also received manual therapy; which I was not interested in the changes of manual therapy could make on subjects with LSS. I was more interested in the changes made when incorporating BWSTT with a back stabilization exercise program for individuals with LSS. Each group received completely different therapeutic interventions making it difficult to attribute the changes in symptoms to either the BWSTT, back exercises or manual therapy. The results of this study suggest neither intervention FExWG or MPTE_xWG will improve patients’ functional capabilities or decrease pain after 6 weeks; therefore there is no real benefit of either intervention for adults with LSS who are not appropriate for surgical interventions. Further research is needed to compare BWSTT and back stabilization exercises to a program of solely back stabilization exercises to find evidence related to my clinical question.

Population— 58 adults >50 y.o. with lumbar spinal stenosis

Intervention— Manual PT, BWS treadmill walking, and exercise

Comparison— Flexion exercises, treadmill walking program, ultrasound

Outcomes— Perceived recovery, modified Oswestry, numerical pain rating, measure of satisfaction, treadmill test.

PICO match: The article PICO does not match with my clinical PICO. The major difference being the inclusion of manual therapy with body weight support treadmill training.

Blinding: Research assistants were blinded to group allocation. The authors did not mention whether the subjects were blinded. Therefore, it is uncertain if the subjects were aware of whether they were in the treatment or control group. There were treating physical therapists and physical therapy assistants who performed interventions and assessments, but the authors once again did not mention if they were blinded to group allocation so none is assumed.

Controls: This study did not have a true control group.

Randomization: The subjects were randomized into 2 groups using a computer-generated randomization scheme into blocks of 20 subjects. The authors described concealing the results of the randomization in numbered sealed envelopes of group allocation. The treating therapist opened the envelopes to reveal the results of the randomization. This randomization was successful as indicated by the fact that the groups did not have any significant differences at baseline.

Study: This prospective randomized controlled trial obtained subjects by convenience sampling who were screened for lumbar spinal stenosis (LSS) by a physical examination and MRI findings. There were 58 subjects (27 females) randomly assigned into FExWG group (n=29) and MPTEExWG (n=29). Inclusionary criteria included: pain in the lumbopelvic region and lower extremities, >50 years old and MRI findings consistent with LSS. Subject's rating of sitting as a better position for symptom severity than standing or walking. Exclusionary criteria included: severe vascular, pulmonary, or coronary artery disease limiting to their walking tolerance test or walking program, previous lumbar spinal surgery included fusion, history of spinal tumors, infection, or other lumbar vertebral fractures other than spondylolysis or spondylolisthesis; contraindications for lumbar spine MRI; and signs and symptoms suggestive of potential nonbenign or pathologic condition as the origin of the symptoms.

Each subject was scheduled for 2 times a week for 6 weeks for 45-60 minute PT session. In addition to PT all subjects were asked to take a daily walk at a pace and distance that did not irritate lower extremity symptoms and to perform home exercise program. The subjects were also required to keep exercise logs during the 6 week treatment period, as well as provide a self report of their exercise compliance during the 6 week intervention period and from 6 weeks to 1 year.

The FExWG group interventions included lumbar flexion exercises, treadmill walking program, and sub-therapeutic ultrasound. Flexion exercises included three 30 second single and double-knee-to-chest exercises for PT and HEP. During each session subjects were to walk on a level treadmill at a selected comfortable walking pace and stop when walking symptoms reached the point that would typically cause them to stop walking during normal ambulation. The duration of each treadmill session was based on the subject's tolerance for that day and could extend up to 45 mins.

The MPTEExWG group was treated by experienced manual therapists. Treatment included manual physical therapy to thoracic and lumbar spine, pelvis and lower extremities and BWS treadmill walking program. Manual therapy techniques were not standardized; they were individualized to each patient. Subjects were instructed to perform the same flexion exercises as the FExWG. To address mobility, exercises were to be done 3x for 30 seconds and stretching exercises 3 reps with 30 second holds. Strengthening was tailored to each individual. The amount of support used for each subject's treadmill session is based on the minimal amount of unloading required to minimize symptoms and to walk at a comfortable rate. All subjects were allowed to continue with previous prescribed medications or over the counter meds for symptoms associated with LSS, but were advised not to change the dosage of medications during the 6 week treatment period. No epidural steroid injections were performed from 6 weeks before the baseline to end of the treatment period.

Outcome measures: Outcomes were measured at three time points: baseline, after the 6 week intervention period and at one year. The outcome measures most relevant to my clinical question are the Modified Oswestry Disability Index (OSW) and Numerical Pain Rating Scale (NPRS) for average thigh/ leg pain. The authors state that there are currently no outcome measures specifically validated for subjects with LSS treated with nonsurgical interventions.

However, the NPRS and OSW have been validated in many other patient populations. Although the authors did not discuss a threshold for minimal clinically important difference (MCID) on the NPRS, the MCID had been reported as a 2 point change (Pinto et al. 2007). The OWS was used to assess different aspects of function. Reliability and validity of OWS were not discussed; however, Fritz et al. reported that a 6 point change is needed to be considered a valid outcome measure (Fritz and Irrgang, 2001).

Study losses: 100% of the subjects completed the intervention up to the 6 week follow up. Three subjects who met all criteria dropped out after the 6 week follow up for reasons unrelated to the study, a 5% total study loss (2 from the FExWG, 1 from the MPTEExWG). For the long term follow up questionnaire, 3 subjects in each group were lost to follow up (19% total study loss), 2 subjects in the MPTEExWG had died, and 1 subject failed to respond to the mailing and phone contact. One subject did not perform the treadmill (TM) testing portion due to concerns of hypertension. Two subjects did not perform the test at the 6 week and 1 year TM tests due to seasonal allergy exacerbation and unrelated grand mal seizure. Nine other subjects did not perform the TM test at 1 year due to death, 3 developed cardiac conditions classified as absolute contraindications per ACSM guidelines and 5 refused. The authors did perform an intention-to-treat analysis and they carried forward the last available data point.

Summary of internal validity: Overall, this study had adequate internal validity. All subjects were successfully randomized into two groups and equal at baseline. An intention-to-treat analysis was performed. In addition, blinding of research assistants and minimal subject loss (5%) support good internal validity of this study. Although, the authors did not report the reliability of any of the outcome measures further research has shown the OWS and NPRS to be reliable (Fritz and Irrgang, 2001; Pinto et al. 2007). Some threats to internal validity are the PTs and PTAs were not blinded to group allocation. The primary threat to internal validity was the difference in exercises between the two groups. The MPTEExWG received manual therapy addressing mobility and strength making it difficult to determine if the use of the BWS treadmill actually provided relief and change in symptoms or if those changes were due to the manual treatment. It would have been more equitable if the FExWG received manual treatments as well, allowing the outcome measures to be attributed to the intervention of the BWS treadmill.

Evidence: OWS and NPRS were measured at the 6 week and 1 year time points because I am interested in immediate and long term effects after the 6 week intervention.

Table 1. Comparison of FExWG and MPTEExWG scores for OWS at 6 weeks.

	Baseline	6 wks	Mean change scores	Met MCID	Effect Size Between Groups [95% CI]	Mean Difference [95% CI]
FExWG	38	32	6	Yes	0.29 [-0.23 – 0.8]	3.39 [-3.70 – 11.56]
MPTEExWG	35	25	10	Yes		

Table 1 illustrates the effect size of the change scores between groups from baseline to 6 weeks for the OWS. Because the authors did not present raw data for the OWS, mean scores were extrapolated from the graphs at baseline and 6 week post test due to notable similarities between groups at baseline. Using the MCID of 6 points on the OWS score, both groups met the MCID. Confidence intervals (CI) surrounding the effect size between groups were calculated by the standard deviations noted in the article. The calculated 95% CI for effect size

between groups is -0.23 to 0.8 which indicates intervals did overlap; therefore subjects could have gotten worse with treatment. The effect size is 0.29 indicating a small to medium effect that the treatment would have changed the results to the MPTEExWG group. The calculated mean difference (95% CI) for OWS is 3.39 (-3.70 – 11.56), indicating the mean difference could have been as low as -3.7, which is much less than the MCID, or as high as 11.56, which is well above the MCID. Therefore, we cannot be sure if the difference between groups met the MCID. However, its inconclusive to whether these findings are truly not statistically significant due to the population used for the given MCID is much younger than the subjects in this study. Having the 95% CI go negative indicates that subjects could have gotten worse with treatment.

Table 2. Comparison of FExWG and MPTEExWG scores for OWS at 1 year.

	6 wks	1 year	Mean change score	Met MCID	Effect Size Between Groups [95% CI]	Mean Difference [95%CI]
FExWG	32	33	+1	No	0.15 [-0.36 – 0.67]	2.11 [-5.52 – 9.74]
MPTEExWG	25	28	+3	No		

Table 2 illustrates the between group change scores from 6 weeks to 1 year for the FExWG and MPTEExWG groups for the OWS functional survey. Again the authors did not present raw data for the OWS, and mean scores were extrapolated from a graph and notable similarities between groups at baseline. Neither group met the MCID, in fact each group showed to get worse, which is also shown by the 95% CI overlapping and crossing zero. Therefore, there is no statistically significant difference between groups for the OWS at the 1 year follow-up.

Table 3. Comparison of FExWG and MPTEExWG scores for NPRS at 6 weeks.

	Baseline	6 wks	Mean change scores	Met MCID	Effect Size Between Groups [95% CI]	Mean Difference [95%CI]
FExWG	5.5	4.25	1.25	No	0.17 [-0.34 – 0.69]	0.4 [-0.87 – 1.67]
MPTEExWG	5	3.75	1.25	No		

Table 3 illustrates the between group change scores from baseline to 6 weeks for the FExWG and MPTEExWG groups for the NPRS. Because the authors did not provide raw data for NPRS; mean scores were extrapolated from a graph and notable similarities between groups at baseline. Using the MCID of improvement of 2 points, neither group met the MCID. The 95% CI surrounding the effect size between groups were calculated to -0.34 to 0.69 which indicates the intervals did overlap, which could mean subjects had gotten worse with treatment. The effect size is 0.17 indicating a small effect that the treatment would have changed the results to either group, suggesting no statistical significance. The mean difference (95% CI) for the NPRS is 0.4 (-0.87 to 1.67) indicating that neither group improved enough to meet the MCID. Also, the 95% CI went negative indicating subjects' pain level could have increased due to the intervention.

Table 4. Comparison of FExWG and MPTEExWG scores for NPRS at 1 year.

	6 weeks	1 year	Mean change score	Met MCID	Effect Size Between Groups [95% CI]	Mean Difference [95%CI]
FExWG	4.25	4.25	0	No	0.09	0.2

					[0.43 – 0.6]	[-1.07 to 1.47]
MPTE _x WG	3.75	4.25	-0.5	No		

Table 4 illustrates the between group change scores from 6 weeks to 1 year post participation in therapy for the FExWG and MPTE_xWG groups for the NPRS. Once again, the authors did not provide raw data for NPRS; mean scores were extrapolated from a graph and notable similarities between groups at baseline. Using the MCID of 2, it showed neither group met the MCID, actually that the MPTE_xWG group may have gotten worse. There is a very small effect size for between groups of 0.09 and 95% CI of -1.07 to 1.47 indicating the intervals did overlap where subjects could have gotten worse which is shown with the MPTE_xWG group. The mean difference between groups (95% CI) is 0.2 (-1.07 to 1.47) which is further from meeting the MCID score at 6 weeks. This further explains that neither intervention provided long term effects in reducing pain.

Applicability of study results:

Similarity to my patients: The age ranges of subjects were a very good match to my clinical PICO. They were adults older than 65 years who were diagnosis with lumbar spinal stenosis and referred by a physician, which is a similar population seen in the clinic.

Benefits vs. Costs: The evidence of this study shows improvements for both groups after 6 weeks; however, the MPTE_xWG showed greater improvements in the OWS. Given the difference in outcomes after 6 weeks for the OWS it is unknown if these benefits could be gained without the use of the BWS treadmill training or whether these improvements could be achieved solely through manual therapy or in addition with a walking program. Since both groups received the same number of treatment sessions, there would be no appreciable differences in financial costs. No adverse responses to interventions were reported.

Feasibility of treatment: The use of BWS treadmill training with manual therapy and flexion exercises could possibly be used in a clinic setting, if a BWS treadmill was available and experienced manual therapist were on staff. The protocol for each group was clearly described. The subjects were treated 2 times a week for 6 weeks (12 sessions), which is likely within the range insurance is willing to pay. There was no report by the authors or subjects of either intervention being painful.

Summary of external validity: The subjects sample is similar to patients treated in an outpatient clinic and had similar symptom presentation as seen in the clinic. The subjects were all referred by primary care physicians for lumbar spinal stenosis, which is often how clinics receive their patients. Also, the use of convenience instead of random sampling slightly decreases the ability to generalize. The internal validity was reasonable; however the lack of a “true” control group decreases the ability to generalize the results to the BWS treadmill training intervention and not other interventions of the treatment program.

Article # 2: Pua, Y.H., Cai, C.C., Lim, K.C.(2007) Treadmill walking with body weight support is no more effective than cycling when added to an exercise program for lumbar spinal stenosis: a randomized controlled trial. *Australian Journal of Physiotherapy* 53: 83-89.

Clinical Bottom Line:

In this randomized controlled trial with 68 adults with LSS results demonstrate, there is insufficient evidence to suggest that for patients older than 65 years old who have LSS, an intervention of BWSTT, mechanical traction and an exercise program does not result in better outcomes than cycling, mechanical traction and an exercise program. The modified Oswestry Disability Index (ODI) effect size (95% CI) was 0.19 (-0.29 – 0.66) and the effect size for Roland-Morris Disability Questionnaire (RMQ) was 0.02 (-0.45 – 0.50). The Visual Analog Scale (VAS) effect size (95% CI) was 0.06 (-0.42 – 0.53) indicating a very small effect size, and the negative lower boundary of the 95% CI indicates there may have been a detrimental effect. There were no statistically significant mean differences between groups at 6 weeks for the ODI, RMQ, or VAS. All 95% CIs crossed zero indicating subjects could have gotten worse with either intervention. The number needed to treat (NNT) to show improvements on the ODI was 45. Twenty-one subjects (29%) did not complete measurements at 6 weeks and one subject withdrew from the BWSTT group due to increased pain with walking. The study had fair internal validity due to successful randomization into groups and blinding of assessor. The main concern of this article is a lack of a true control group and use of mechanical traction. The use of mechanical lumbar traction takes away the significance of using BWSTT. My main interest was finding the benefits of using the BWSTT to elongate and unload the spine. By using mechanical traction, which is a similar intervention, makes it difficult to determine if the changes in scores were due to the BWSTT intervention or the mechanical traction. A true control group would have received solely an exercise program without the addition of lumbar traction and cycling. The results of this study suggest neither BWSTT nor cycling in conjunction with an exercise program will improve patients' functional abilities or reduce pain after 6 weeks. Therefore there is no real benefit of either intervention for adults with LSS who do not qualify for surgery.

Population— 68 adults with LSS/LBP

Intervention— Body weight support treadmill walking and exercise program

Comparison— Cycling and exercise program

Outcomes— Modified Oswestry Disability Index, Roland-Morris Disability Questionnaire, visual analogue scale (VAS), patient perceived benefit.

PICO match: The article PICO is relatively close to my clinical PICO, with the major difference being comparison of BWS treadmill walking and cycling.

Blinding: The authors mentioned the physical therapists delivering the interventions were not blinded to group allocation. Also, subjects were not blinded to interventions due to the informed consent process. Blinding was done to the assessor who performed measurements at 3 and 6 weeks. Subjects were instructed not to reveal information about their interventions to the assessor.

Controls: The study did not have an appropriate control group. Each group received the same modalities, exercises and HEP, the differences between groups were BWS treadmill walking or cycling.

Randomization: The subjects were randomized into 2 groups using a computer-generated table of random numbers to perform block randomization of 4 and 6 per block. This randomization was successful as indicated by the fact that the groups did not have any significant differences at baseline.

Study: This was a prospective randomized controlled study of 68 subjects (38 females) obtained using convenience sampling from a physical therapy outpatient clinic of a large tertiary institution. The subjects were randomized into two groups: treadmill (n=33) and cycling (n=35), using a block of four and six. Both groups performed an exercise program prior to either cycling or BWS treadmill walking. Each session began with 20 minutes of heat therapy using a shortwave diathermy machine. Patients were then positioned in the Fowler's position for 15 minutes of mechanical lumbar traction which was set at 30 seconds on and 10 seconds off. Traction was set at 30-40% of the subject's body weight depending on the subjects response, off cycle was set at 10% of body weight. Subjects were all given the same home exercise program (HEP), which they were instructed on during the first intervention session; the HEP was to be performed daily for 6 weeks. The treadmill group trained with the Biodex unweighting system; during the first two weeks subjects walked at a comfortable pace with 30-40% body weight support. In weeks 3-6 subjects were encouraged to walk at a moderate intensity (11-15 point on Borg rating of perceived exertion scale). Each treadmill session was limited by the subject's tolerance or a maximum of 30 minutes. The cycling group trained on an upright bike. During the first two weeks subjects cycled at a comfortable pace at 50-60 rpm. Subjects were instructed to keep a flexed posture and avoid lumbar extension while riding. In weeks 3-6 subjects were encouraged to cycle at a moderate intensity and each session was limited by participant tolerance or maximum of 30 minutes.

Inclusion criteria were at least 50 years of age, a history of LBP with radiating or non-radiating symptoms, a body mass index less than 38 kg/m², evidence of lumbar spinal stenosis on MRI, no cognitive impairments, LBP while walking and LBP during sustained (30 sec) spinal extension in the quadruped position, and relief of LBP or lower extremity symptoms in sitting. Exclusion criteria included subjects who had symptoms arising from neoplastic conditions, severe osteoporosis, spondylolisthesis with greater than 5 mm of slippage, pulmonary or vascular disease, or had undergone surgery for LSS or to the lower extremities.

Outcome measures: Outcomes were measured at baseline, 3 and 6 weeks. The outcome measures most relevant to my clinical question are the modified ODI, RMQ and VAS (100-mm), measured at 6 weeks. The authors did report and cite reliability and validity for the modified ODI. The authors stated subjects with at least an 8 point improvement in their modified ODI or 800 meters on the walking item of the questionnaire were categorized as having improved. The authors did not mention an MCID for RMQ or VAS, however, Stratford et al reports a 5 point change to show clinical significant changes for the RMQ and VAS has been validated in other patient populations (Stratford et al., 1996, Childs et al., 2005). Although the authors did not discuss a threshold for a MCID on the VAS, the MCID has been reported as slightly greater than 30% change in the VAS. Thus, for this study, the MCID in the 100 mm VAS is roughly 30 points.

Study losses: Twelve subjects (18%) did not complete measurements at week 3, however I was not interested in this short term data. Twenty-one subjects (29%) did not complete measurements at 6 weeks. One subject withdrew from the treadmill walking group due to increased pain with walking, reasons for other dropouts was not discussed. The authors did do an intention to treat analysis.

Summary of internal validity: Overall, this study had fair internal validity. All subjects were successfully randomized into two groups and given the same instructions. Blinding of the assessor doing the assessments minimized potential rater bias. The authors did report and cite the reliability of the outcome measures for the ODI and further research has shown the VAS and RMQ to be a reliable outcome measure. Some threats to internal validity were that the PTs and subjects were not blinded to group allocation. Subject loss and non compliance were minimal threats to internal validity as the authors did perform an intention-to-treat analysis. A lack of a control group poses a threat to the internal validity as it is hard to generalize the effects of the intervention of BWS treadmill walking.

Evidence: The outcome measures most relevant to my clinical question are the modified ODI, RMQ and VAS (100-mm), measured at 6 weeks.

Table 5: Comparison of interventions of ODI, RMQ, and VAS after 6 weeks.

	Effect Size Between Groups [95% CI]	Mean Difference [95% CI]
ODI	0.19 [-0.29 – 0.66]	2.9 [-5.06 – 10.86]
RMQ	0.02 [-0.45 – 0.50]	0.1 [-2.14 – 2.34]
VAS	0.06 [-0.42 – 0.53]	1 [-8.29 – 10.29]

Table 5 illustrates the between group change scores from baseline to 6 weeks for the ODI, RMQ, and VAS. Because the authors presented means and standard deviations for the ODI, RMQ and VAS effect size, mean difference and 95% CI could be calculated. The ODI effect size (95% CI) was 0.19 (-0.29 – 0.66) and the effect size for RMQ was 0.02 (-0.45 – 0.50). The effect size did not favor either group and there was overlap of the 95% CIs for the effect size, suggesting no real differences between interventions. The VAS effect size (95% CI) was 0.06 (-0.42 – 0.53) indicating a very small effect size that either intervention would have reduced pain for subjects. This is strengthened by the fact that the 95% CI crossed zero; therefore subject’s pain scores could have gotten worse or their function capabilities could have declined. The mean difference between groups was calculated for the ODI, RMQ and VAS respectively: 2.9 (-5.06 – 10.86); 0.1 (-2.14 – 2.34); and 1 (-8.29 – 10.29). No statistically significant difference was found between groups for any of these outcome measures. Therefore, no further analysis is necessary.

Table 6: Risk Ratio for functional improvements for LSS after 6 weeks.

	CER	EER	ARR	RRR	NNT	Odds Ratio
6 Weeks	0.63	0.61	0.02	0.04	44.42	0.91

Table 6 shows the risk ratio for functional improvements for LSS after 6 weeks of treatment. The Control Event Rate (CER) is the rate in which an event occurs in the control group without the experimental treatment. The CER in this study implies there is a 63% chance of getting better within 6 weeks with cycling and flexion exercises. The Experimental Event Rate (ERR) is the rate an event occurs in the experimental treatment group. In 6 weeks after BWSTT – the EER suggests there is a 61% chance of getting better. The Absolute Risk Reduction (ARR) is the amount the risk decreases from the control group to the experimental group. The ARR states in this study, the chance of getting better is 2% within 6 weeks with BWSTT for LSS. The Relative Risk Reduction (RRR) is the amount the risk would decrease in the general population if everyone got the treatment. In the study, the RRR shows in general the chance of getting better 4% within 6 weeks with the use of BWSTT. The Number Needed to Treat (NNT) is the number who must be treated in order to have one successful outcome. The NNT (95% CI) in this study proposes for every 45 people treated, there will be 1 less person who has complaints of LSS (-4.8 – 3.9). The Odds Ratio (OR) is how much more likely an event is in the treatment group as compared to the non-treatment group. The OR proposes there is a 91% chance of not getting better in 6 weeks with the BWSTT for LSS.

Applicability of study results:

Similarity to my patients: The average age range of subjects was younger than I was looking to compare to my clinical PICO; the average age was 58 years (SD 8). Otherwise they were a close match to my clinical PICO, meeting inclusion criteria.

Benefits vs. Costs: Since both groups received the same number of treatment sessions, there would be no appreciable differences in financial cost. It is hard to summarize whether the intervention would have been beneficial had there not been traction provided prior to the interventions under analysis. The purpose of the BWS treadmill walking was to unload the spine to reduce the compressive forces during ambulation and decrease the pain, which is similar to the mechanics of lumbar traction. Without traction prior to cycling or BWS treadmill walking, would there be such similarities in outcome measures. One subject reported having to withdraw from the treatment due to increased pain while walking on the treadmill. Twenty six subjects reported that their back and leg pain prevented them from walking more than 400 meters. At 6 weeks evidence reports no considerable differences between the BWS treadmill group and cycling, therefore, neither intervention has proven to be affective for treating LSS.

Feasibility of treatment: The techniques and exercise program used in this study are very realistic for most clinical settings. On the other hand, the exercises were not clearly described, unless one is a member of *Australian Journal of Physiotherapy* you are unable to access the Appendix mentioned in the article. Otherwise, the protocols for both interventions were clearly described. The fact that subjects were asked to comply with a HEP would be imperative for successful outcomes. However, it should be noted in other studies sited there are high dropout rates in studies of exercise in older adults with low back symptoms. Given these findings it raises a question about the true feasibility of this approach. Both groups received interventions 2 times a week for 6 weeks (12 sessions) which is within the range that insurance would allow.

Summary of external validity: The subject sample is similar to patients treated in an outpatient orthopedic clinic and had similar clinical presentation. The lack of a detailed description of the exercise program undermines the ability for deciding whether it could be generalized to clinical practice. Because the authors used convenience sampling instead of random sampling, I cannot be as confident that the results are truly representative of the general population seen in clinic. The internal validity was reasonable; however the lack of a “true” control group decreases the ability to generalize the results of the BWS treadmill walking intervention and not other interventions provided during treatment.

Synthesis/Discussion

I assessed the methodological quality of these 2 studies using the PEDro scale. Whitman, et al and Pua, et al both scored 8/10. Both studies provided strong evidence for determining interventions in making changes in subjects with LSS.

The eligibility criteria for the articles chosen were somewhat broad to allow finding of 2 articles that were pertinent to my clinical question. When limiting my search to articles that were in English, had subjects who were diagnosed with LSS, included BWSTT as one intervention and had a functional index survey and pain scale outcome measures. This selection process produced 2 RCTs that most closely matched my clinical PICO.

Both studies used body weight support treadmill walking as one of their interventions over a 6 week period (12 sessions) for treatment of LLS. Treatment parameters varied

between articles. Whitman et al. had BWSTT with manual therapy and flexion exercises as one of their interventions and Pua et al. had BWSTT, manual traction and an exercise program. Also, each article did not have a true compare group, as neither group solely received therapeutic exercises, the Whitman et al. study, performed lumbar flexion exercises, treadmill walking, and sub-therapeutic ultrasound. The Pua et al. compare group participated in cycling, mechanical traction and exercise program. The Whitman et al. study had subjects walk at a comfortable pace and distance that did not irritate lower extremity symptoms, in addition to their PT sessions. The amount of body weight support used for each study varied; Whitman et al. unloaded the minimal amount of weight to minimize symptoms during walking. Pua et al. had 30-40% body weight support during walking and had subjects walk at moderate intensity. Subjects were allowed in the Whitman et al. study to continue with previous prescribed medication or over the counter meds for symptoms associated with LSS.

Table 7 shows the effect size and mean differences between groups. Both Whitman et al. and Pua et al. had a small effect size with 95% CIs which cross zero, indicating that interventions were not successful in making a change in subjects with LSS.

However, when extrapolating data from the Whitman et al. study mean change scores indicated that both interventions met the MCID for OWS at 6 weeks, demonstrating clinically significant improvements in functional capabilities. Calculated mean differences for both articles indicated no statistically significant for the Oswestry or pain scores.

Table 7: Comparison of effect size and mean difference Oswestry Index and Pain scores f

Articles	OWS/ ODI Effect Size Between Groups [95% CI]	NPRS/ VAS Effect Size Between Groups [95% CI]	OWS / ODI Mean Difference [95% CI]	NPRS/ VAS Mean Difference [95% CI]
Whitman et. al	0.29 [-0.23 – 0.8]	0.17 [-0.34 – 0.69]	3.39 [-3.70 –11.56]	0.4 [-0.87 – 1.67]
Pua et. al	0.19 [-0.29 – 0.66]	0.06 [-0.42 – 0.53]	2.9 [-5.06 – 10.86]	1 [-8.29 - 10.29]

Table 8 shows the results of the Pua et al. study demonstrating no clinical significant improvements in Oswestry functional index. The study resulted in a NNT of 45, allowing us to conclude that there was not a clinically significant due to body weight support treadmill walking.

Table 8. Comparison of Modified Oswestry Disability Index

Articles	ARR (95% CI)	NNT (95% CI)	RR (95% CI)
Pua <i>et al.</i>	0.02	44.42(-4.8 – 3.9)	0.04

The evidence calculated for both studies showed no significant statistics for incorporating BWSTT as an intervention for older adults with LSS. Therefore, these articles would not affect my treatment in anyway and I would not incorporate BWSTT into my treatment program for adults with LSS. Further research is needed with a more appropriate control group, in order to accept any potential results.

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