Effectiveness of Lumbar Traction With routine Conservative Treatment in Acute Herniated Disc Syndrome

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Objective : *To assess the effectiveness of lumbar traction with routine conservative treatment in acute herniated disc syndrome.*
Design : *Randomized double-blind controlled trial.*
Setting : *Outpatient clinic of physical medicine and rehabilitation.*
Method : *120 participants who met the diagnostic criteria of acute herniated disc syndrome were randomized into two groups. The study group received treated traction, and the control group received sham traction. All patients had routine conservative treatments (consisting of NSAIDs, instruction of proper back activity and precaution, back exercise, and heat modality). The main outcome measurement was the Oswestry score, which was collected on the first day and at the 4 th week of the treatment. At the end of the study, all patients recorded global improvement and satisfaction.*
Results : *Of 120 patients divided into two groups equally, 12 and 6 cases in the control and intervention groups dropped out of the study. The mean (SD) change of the Oswestry score were 19.25(15.9) and 25.25(16.68) in control and intervention groups respectively. There was no significant difference between the two groups with the p-value of 0.067 and 95%CI of -0.42-12.43. Approximately 89% of patients in each group had improvement of their symptoms, and 90% in each group were satisfied with lumbar traction. Co-intervention with heat modality, NSAIDs use and back exercise did not differ between the two groups.*
Conclusion : *The data do not support the benefit of traction for patients with acute herniated disc syndrome. The patient can be conservatively treated at home with proper instruction.*

Keywords : *Lumbar traction, Herniated disc syndrome, Herniated disc*

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Low back pain, is a widespread, disable, and poorly understood condition[1]that affects 70-90% of people at some time in their lives[2].It affects both men and women equally, and the onset most commonly occurs between the age of 30 and 50 years[3]. The effect of this condition is a burden to society in terms of missed workdays and direct and indirect health care costs[4].

Sciatica caused by herniation of a lumbar disc is the most common cause of low back pain and radicular pain in the working-age population[5], accounting for 10% of low back pain episodes[6, 7].

For patients with a lumbar herniated disc but without indication for immediate operative intervention such as cauda equina syndrome, progressive neurologic deficit or intractable radiculopathy; a course of nonoperative treatment is reasonable. In most cases, these patients have improvement of their symptoms over time and do not need an operative intervention. These conservative treatments include bed rest, medication, physical therapy and epidural steroid injections. Current recommendations include short-term bed rest as needed with early mobilization for most patients with back pain. Although physical therapy is often recommended, there is a paucity of evidence demonstrating its efficacy in either condition. Even in nonspecific acute low back pain, it is still doubtful that the formal physical therapy is of any clinical benefit[1,8-10]. No RCTs, however, have assessed the efficacy of formal physical therapy in lumbar radiculopathy with disc herniation.

The efficacy of many physiotherapeutic interventions is questionable[11,12]. One of the treatment options is traction, which can be combined with other techniques, such as massage exercise, electro-

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therapy or heat. The following remarks concern the methodology of the studies. Firstly, 30% of the studies did not mask the patients or observers. Secondly, various trials reported nonsignificant differences between groups, which may be explained by the inadequate sample size. Finally, some methodology shortcomings may result from incomplete reporting and the trials themselves. There seems to be insufficient evidence supporting the effectiveness of most of the conservative treatments for sciatica with or without underlying disc herniation. There also has been no evidence showing that traction, NSAIDs, or intramuscular steroids is superior to placebo.

Traction is widely used for the treatment of lumbar spine conditions. The proposed mechanical effects of traction are vertebral separation and widening of the intervertebral foramen[13, 14]. These mechanisms suggest short-term rather than long-term effects or benefits. From a systematic review of traction for treating LBP, there were many pitfalls in the methodological quality of RCTs. Methodological flaws concerned insufficient description of randomization procedure, small sample size, incomparability of cointervention, no attempts to blind patients, and no attempts to blind outcome measurement or failure to include a blinded assessor[15]. So far, there has been no clear-cut information about the mechanism or evidence for any specific effect of lumbar traction. However, there is no conclusive evidence that traction is an ineffective therapy for back pain either[15].

Material and Method

All of the patients who met the diagnostic criteria of acute herniated disc syndrome at the outpatient clinic, Department of Rehabilitation Medicine of 4 institutes (Pranangklao Hospital, Sirindhorn National Medical Rehabilitation Centre, King Chulalongkorn Memorial Hospital and Ramathibodi Hospital) were recruited for the present study. The patients were allocated into two groups by simple randomization using random number tables, sealed in envelopes. The diagnostic criteria of acute herniated disc syndrome were based on the history of low back pain for less than 3 months[16] and at least one of the three findings:1. History of back pain worsened by coughing, sneezing, straining or presented with sciatic pain (pain radiating into the posterior thigh and below knee to foot in L5 or S1 dermatomes)[4] or 2.Physical examination revealed positive tension signs test such as sciatica stretch test (SLRT)[19] or 3.MRI or myelogram showing evidence of a lumbar disc bulging or protrusion[17]. The inclusion criteria were patient age more than 18 years old, both sexes, suffered from acute low back pain with or without radiating pain for less than 3 months, baseline Oswestry score range from 20-80 and meet the diagnostic criteria of acute herniated disc syndrome. The exclusion criteria were a patient who had received previous lumbar traction for acute low back pain problem for this episode, previous surgery for low back pain problem, suspected malignancy, pregnancy, fracture of lumbar spine or progressive neurological deficit. The sample size calculated from the difference of mean change between the two groups which showed clinical significance was 8[18], the standard deviation of the change in score of the two groups was 14. For 2 sided α of 0.05, power of study was 80 % and are assumed 20% drop out rate so the total number of patients equaled 120. All patients received lumbar traction under supervision of a physiotherapist. The setting of traction was intermittent hold for 45 seconds, then rest for 30 seconds. The patients' position was in 90° hip flexion and 90° knee flexion. The physiotherapist applied the traction force of 35-50% of the body weight in the intervention group. In the control group, the traction force was less than 20% of body weight, and the patient would feel a little pulling from the harness. For each session, the physiotherapist recorded the date, applied duration, force of traction and complication if it occurred. Patients attended as are OPD case for 3 times per week and 20 minutes per session. All patients received the NSAIDs, booklet-containing advice on the appropriate activity for protection of back pain, back exercise (such as back mobilization, flexion and extension exercises) and home used superficial heat. They were asked to record the daily use of NSAIDs, heat and back exercise.

Measurement

The baseline data included age, gender, degree of straight - leg raising (SLRT), history of pain radiating below the knee, body mass index, number of previous low back pain episodes. The Oswestry score was collected 2 times at baseline and at the 4th week. At the end of the study, the patient responded to these 2 questions about the global improvement and patient's the satisfaction.

The compliance of traction application was divided into 3 categories. Good was defined as the patient receiving total traction of 9-12 times, fair: 6-8 times and poor: 1-5 times. The compliance of back exercise was defined in 3 groups. Good was defined as the patient being able to complete 40 repetition sets

of back exercise per day for 2-28 days, fair: 14-20 days and poor: 1-3 days.

Analysis

The baseline data were analyzed by descriptive statistics. Unpaired t-test was used to compare the Oswestry score change between the two groups.

The Chi-square for trend was used to compare global improvement and patient's satisfaction between the two groups.

The unpaired t-test was used to compare the heat usage and NSAIDs usage used the nonparametric test to compare between the two groups.

The statistical analysis was carried out according to the intention to treat principle.

Results

One hundred and twenty participants diagnosed with lumbar disc syndrome, who met the criteria were enrolled into the study between March 2003-January 2004 at the outpatient clinic, Department of Physical Medicine and Rehabilitation of 4 institutes:Pranangklao Hospital, Sirindhorn National Medical Rehabilitation Centre, King Chulalongkorn Memorial Hospital and Ramathibodi Hospital were 45, 10, 10 and 55 respectively.

The 120 cases were allocated to the intervention and control groups. The subjects' progress through the phase of randomized trial is demonstrated in Fig. 1.

Baseline characteristics of both groups were comparable regarding gender, age, number of previous LBP episodes, history of radiating pain, degree of SLRT, present mild neurological deficit, and body mass index. The baseline Oswestry score of both groups had statistically significant difference between the two groups at p-value 0.013 (Table 1). At the end of the study, the number of drop outs in the control and intervention groups was 12 and 6 cases, respectively.

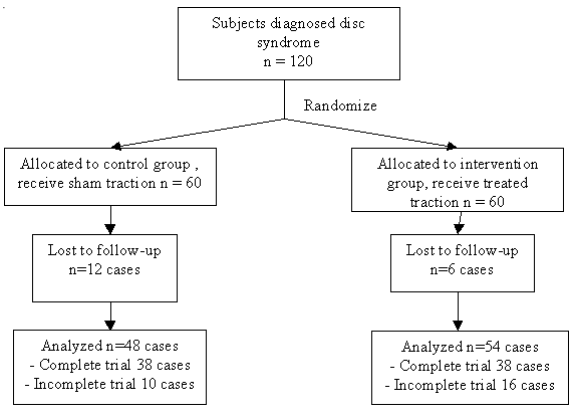

Fig. 1 Flow diagram of subject progress through the phase of randomized trial

Table 2 shows the results of the Oswestry score in both groups. The mean (SD) changes of the Oswestry score were 19.25(15.9) and 25.25(16.68) in the control and intervention groups; respectively. There was no statisticall significance in means change of the Oswestry score between these two groups (6.0; 95%CI -0.42,12.43; p = 0.067).

The data of global improvement and satisfaction of both groups are presented in number and percentage in Table 3.

For global improvement, about 70% in each group had significant improvement of their symptoms. There were 4% in both groups who rated themselves as being worse.

There were 90.9% in the control and 94.2% in the intervention groups who were satisfied with lumbar traction.

The statistic was tested to compare the difference of global improvement and satisfaction between the two groups. There was no statistically significant difference on global improvement and satisfaction between the two groups (P-value > 0.05).

In Table 4, there were 38 patients in each group who received the full course for traction. Pain

Table1. Baseline characteristics of the studied patients

Characteristics	Control group	Intervention group	P - value
No. of patients	48	54	
Gender ; Male (%)	26(54.2%)	21(38.9%)	
Female(%)	22(45.8%)	33(61.1%)	
Mean age (years)(SD)	36.71(7.03)	37.83(7.72)	
History of pain radiating (%)			
- No	5(10.4%)	2(3.7%)	
- Radiate below the knee	36(75.0%)	43(79.6%)	
- Radiate above the knee	7(14.6%)	9(16.7%)	
No. of previous LBP episodes(%)			0.549
- First attack	20(41.7%)	27(50.0%)	
- 1-5	22(45.8%)	19(35.0%)	
- 6-10	6(12.5%)	8(15.0%)	
Degree of SLRT(%)			0.400
- Negative	24(50.0%)	19(35.2%)	
- 30	4(8.3%)	9(16.7%)	
- 45	6(12.5%)	8(14.8%)	
- 60	14(29.2%)	18(33.3%)	
Presence of mild neurodeficit (%)			
- Weak EHL	10(20.8%)	8(14.8%)	0.426
- Decreased ankle jerk	1(2.1%)	3(5.6%)	0.367
Mean body mass index (SD)	22.92(3.32)	23.62(4.04)	0.342
Mean baseline Osw score (SD)	40.61(13.94)	47.97(15.32)	0.013
(min-max)	(20-73.33)	(20-80)	

Table 2. Results of Oswestry score in both groups

Oswestry score	Control group (n = 48)	Intervention group (n = 54)	95%CI of the difference	P - value
Mean baseline Osw score(SD) (min-max)	40.61 (13.94) (20-73.33)	47.97 (15.32) (20-80)	7.36 (1.58-13.15)	0.013
Mean 4th wk Osw score (SD) (min-max)	21.36 (17.27) (0-66.67)	22.72 (18.61) (0-84.44)	1.28 (-5.74-8.30)	0.719
Mean Osw diff. (SD) (min-max)	19.25(15.9) (-26.0-68.89)	25.25 (16.68) (-31.11-51.11)	6.00 (-0.421-2.43)	0.067

Table 3. Results of global improvement and satisfaction

	Control group (n=48)	Intervention group (n=54)	P-value
Global improvement (%)			0.889
- Complete recovery	9(18.8%)	9(16.7%)	
- Much improved	25(52.1%)	29(53.7%)	
- Little improved/ unchanged	12(25.0%)	14(25.9%)	
- Little/Much worse	2(4.2%)	2(3.7%)	
Satisfaction (%)			
- Very satisfied	30(68.2%)	34(66.7%)	0.895
- Moderately satisfied	10(22.7%)	14(27.5%)	
- Unsatisfied/ Very unsatisfied	4(9.1%)	3(5.9%)	

Table 4. Compliance and adverse effect of traction

Traction	Control group (n =48)	Intervention group (n=54)	P- value
Compliance (%)			0.369
- Good (received 9-12 times)	38(79.2%)	38(70.4%)	
- Fair (received 6-8 times)	3(6.3%)	8(14.8%)	
- Poor (received 1-5 times)	7(14.6%)	8(14.8%)	
Adverse effect (%)			0.684
- Pain	2(3.3%)	4(6.7%)	

was observed in 4 patients treated with traction and 2 patients in the control group. The statistic test showed no significant difference between the two groups.

Table 5 presents the co-interventions consisting of heat, NSAIDs usage and back exercise. The means (SD) of NSAIDs tablets used were 53.77(24.26) and 50.78(24.79) in the control and the intervention groups, respectively and mean difference (95%CI) was –2.99 (-12.65 – 6.67). The data of back exercise had to be adapted by the combination of data of patients in

Table 5. Co-intervention: heat, NSAIDs and back exercise

	Control group (n=48)	Intervention group (n=54)	P - value
Median heat usage (IQR)	7 (0-32.75)	10 (0-20.25)	0.89
Mean NSAIDs tablets used (SD) (min-max)	53.77(24.26) (0- 84)	50.78(24.79) (4-84)	0.54
Back exercise performance (%)			
- Performed exercise ≥14 days/course (good & fair)	10(20.8%)	6(11.1%)	0.178
- Performed exercise <14 days/course (poor)	38(79.2%)	48(88.9%)	

good and fair into one group, who performed the exercises for more than 14 days per course.

All statistic tests showed no statistically significant difference between the two groups of all co-intervention used.

Discussion

This study was designed to overcome flaw methodological quality of RCTs described in systematic review of traction. Because the sample size of good compliance to traction was inadequate, the power of the study was about 46.3%.

The demographic data of gender, age, frequency of previous LBP, history of radiating pain, degree of SLRT, presence of mild neurodeficit and body mass index were similar in both groups. The drop out rate was about 15% (12 and 6 cases in the control and intervention groups respectively). The reason this group of patients could not come to follow up may be due to most of them being laborers worker who were paid on a daily basis. When they had an acute back pain episode, they were unemployed and could not afford the cost of living in Bangkok. Thus, they had to return to their upcountry homes.

One important factor that affects the effective-

ness of treatment is activity during back pain episode. Patients have to have some adaptation in the workplace to help back protection, but the data is lacking.

The Oswestry scores after treatment were improved over time in both groups. By statistical testing, however, the significant difference in baseline Oswestry score between the two groups might affect the outcome. The baseline Oswestry score in the intervention group was higher than that of the control group. The unequal baseline Oswestry score might be from an unequal number of patients in each institute that lead to unproportional severity distribution of patients' difference in each hospital and unequal distribution of sampling selection by sealed envelopes. The other reason might be the effect from a wide range of the Oswestry scores.

To minimize the effect of the unequal baseline Oswestry score, the percentage change of the Oswestry score was calculated from the Oswestry score change divided by the baseline Oswestry score. The means (SD) of percentage changes of the Oswestry score were 48.86(40.86) and 53.95(34.12) in control and intervention groups respectively. No statistical difference between these two groups was found with mean percentage change difference (95%CI) was 5.09(-9.64-19.83). The other method used to minimize this effect was the statistical test. ANCOVA (one-way analysis of covariance) was used to adjust the baseline difference of the Oswestry score. It showed no statistical difference in mean change of the Oswestry score between the 2 groups with a p-value 0.301.

The per-protocol analysis was challenged. From box plot of the 4th week Oswestry score, there were 3 outliers in the intervention group. If one extreme outlier was discarded due to low compliance of traction, the mean change difference (95%CI) of the Oswestry score change was 7.07(0.98-13.15) with p-value 0.023, and mean percentage change difference (95%CI) was 7.21(-6.96-21.39) with p-value 0.322. This result implied that eventhough one extreme outlier had been discarded; there was no demonstratable effectiveness of the traction.

The compliance of traction was an important factor to provide the effectiveness of intervention. Only 38 patients in each group received a full course (good compliance) of traction. If only the good compliance group were analyzed, there was still no statistical difference between the two groups with p-value 0.116. Regading The adverse effect of traction was minimal in both groups.

Eighty-nine percentage of patients in each group had improvement of symptoms. Two patients in the intervention group had much worse symptom. One patient went home to a rural area, rested for 4 weeks and received only one treatment. Another patient had decreased pain in the second week but she had a severe cough for a few days before follow up at the 4 th week. 90% in each group were satisfied with lumbar traction. The statistic testing for global improvement and satisfaction revealed no statistically significant difference between the two groups. The results mean treated traction didn't provide more improvement or satisfaction.

From the overall result, the analysis of the Oswestry score in many ways included global improvement and satisfaction were similar to the intention to treat analysis. This study provides a valid estimation of the effect of lumbar traction for acute herniated disc syndrome.

Implication of results

In acute herniated disc syndrome the role of lumbar traction seems to be unnecessary. Since the effect of traction did not improve the symptoms patients can receive conservative treatment as a home program and this will save cost and time.

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การศึกษาประสิทธิผลของการใช้เครื่องดึงหลังกับการรักษาแบบไม่ผ่าตัดในผู้ป่วยที่มีอาการจากภาวะหมอนรองกระดูกเคลื่อนเฉียบพลัน

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วัตถุประสงค์ *: ศึกษาประสิทธิผลของการใช้เครื่องดึงหลังกับการรักษาแบบไม่ผ่าตัดในผู้ป่วยที่มีอาการจากภาวะหมอนรองกระดูกเคลื่อนเฉียบพลัน*

รูปแบบการวิจัย *: การทดลองทางคลินิกแบบสุ่มทดลองโดยมีกลุ่มเปรียบเทียบ*

สถานที่ทำการวิจัย *: แผนกผู้ป่วยนอก ภาควิชาเวชศาสตร์ฟื้นฟู*

วิธีการศึกษา *: ผู้เข้าร่วมวิจัยจำนวน 120 รายซึ่งมีอาการปวดหลังจากภาวะหมอนรองกระดูกเคลื่อนเฉียบพลันได้รับการสุ่มเป็น 2 กลุ่ม กลุ่มศึกษาเป็นกลุ่มที่ใช้เครื่องดึงหลังสำหรับรักษา กลุ่มควบคุมใช้เครื่องดึงหลังที่ไม่มีผลในการรักษา ผู้เข้าร่วมวิจัยทุกคนได้รับคำแนะนำเกี่ยวกับท่าทางและกิจกรรมที่เหมาะสมสำหรับอาการปวดหลัง ได้รับยาต้านการอักเสบ คำแนะนำการใช้กระเป๋าน้ำร้อนที่บ้าน และการบริหารหลัง ใช้แบบสอบถาม Oswestry ฉบับภาษาไทยเก็บข้อมูลผู้ป่วยครั้งแรก ผู้เข้าร่วมวิจัยได้รับการรักษาโดยการใช้เครื่องดึงหลังครบ 4 สัปดาห์ตอบแบบสอบถามเกี่ยวกับ Oswestry อีกครั้งหนึ่งรวมทั้งอาการปวดหลังโดยภาพรวม และความพึงพอใจต่อการรักษา*

ผลการศึกษา *: ผู้เข้าร่วมวิจัยมีกลุ่มละ 60 ราย ผู้เข้าร่วมวิจัยจำนวน 18 รายไม่มาติดตามการรักษาแบ่งเป็น 12 ราย ในกลุ่มควบคุม และ 6 รายในกลุ่มทดลอง ค่าเฉลี่ยของคะแนน Oswestry ที่เปลี่ยนแปลง (ค่าเบี่ยงเบนมาตรฐาน) ในกลุ่มควบคุมเท่ากับ 19.25(15.9) และในกลุ่มทดลองเท่ากับ 25.25(16.68) ซึ่งไม่มีความแตกต่างกันทางสถิติที่ p-value 0.067 และร้อยละ 95 ของช่วงความเชื่อมั่นของผลต่างเฉลี่ยเท่ากับ 6.0(-0.42-12.43) ผู้เข้าร่วมวิจัยทั้ง 2 กลุ่ม รู้สึกว่าอาการปวดหลังโดยภาพรวมดีขึ้น ร้อยละ 89 และ ร้อยละ90ของทั้ง 2 กลุ่มพึงพอใจกับการใช้เครื่องดึงหลัง*

สรุปผลการศึกษา *: จากข้อมูลที่ได้จากการวิจัย ไม่สามารถแสดงให้เห็นประสิทธิผลของการใช้เครื่องดึงหลังในผู้ป่วยที่มีอาการจากภาวะหมอนรองกระดูกเคลื่อนเฉียบพลัน*