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นางสาว นพวรรณ แสนเจริญสุทธิกุล

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EFFECTIVENESS OF LUMBAR TRACTION WITH ROUTINE CONSERVATIVE TREATMENT IN ACUTE HERNIATED DISC SYNDROME

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นพวรรณ แสนเจริญสุทธิกุล: การศึกษาประสิทธิผลของการใช้เครื่องดึงหลังกับการรักษาแบบไม่ผ่าตัดในผู้ป่วยที่มีอาการจากภาวะหมอนรองกระดูกเคลื่อนเฉียบพลัน (EFFECTIVENESS OF LUMBAR TRACTION WITH ROUTINE CONSERVATIVE TREATMENT IN ACUTE HERNIATED DISC SYNDROME)

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วัตถุประสงค์ ศึกษาประสิทธิผลของการใช้เครื่องดึงหลังกับการรักษาแบบไม่ผ่าตัดในผู้ป่วยที่มีอาการจากภาวะหมอนรองกระดูกเคลื่อนเฉียบพลัน

รูปแบบการวิจัย การทดลองทางคลินิกแบบสุ่มทดลองโดยมีกลุ่มเปรียบเทียบ

สถานที่ทำการวิจัย แผนกผู้ป่วยนอก ภาควิชาเวชศาสตร์ฟื้นฟู

วิธีการศึกษา ผู้เข้าร่วมวิจัยจำนวน 120 รายซึ่งมีอาการปวดหลังจากภาวะหมอนรองกระดูกเคลื่อนเฉียบพลันได้รับการสุ่มเป็น 2 กลุ่ม กลุ่มศึกษาเป็นกลุ่มที่ใช้เครื่องดึงหลังสำหรับรักษา กลุ่มควบคุมใช้เครื่องดึงหลังที่ไม่มีผลในการรักษา ผู้เข้าร่วมวิจัยทุกคนได้รับคำแนะนำเกี่ยวกับท่าทางและกิจกรรมที่เหมาะสมสำหรับอาการปวดหลัง ได้รับยาต้านการอักเสบ คำแนะนำการใช้กระเป๋าน้ำร้อนที่บ้าน และ การบริหารหลัง ใช้แบบสอบถามOswestry ฉบับภาษาไทยเก็บข้อมูลผู้ป่วยครั้งแรก ผู้เข้าร่วมวิจัยได้รับการรักษาโดยการใช้เครื่องดึงหลังครบ 4 สัปดาห์ตอบแบบสอบถามเกี่ยวกับ Oswestryอีกครั้งหนึ่งรวมทั้งอาการปวดหลังโดยภาพรวม และความพึงพอใจต่อการรักษา

ผลการศึกษา ผู้เข้าร่วมวิจัยมีกลุ่มละ 60 ราย ผู้เข้าร่วมวิจัยจำนวน 18 รายไม่มาติดตามการรักษาแบ่งเป็น 12 รายในกลุ่มควบคุมและ 6 รายในกลุ่มทดลอง ค่าเฉลี่ยของคะแนน Oswestryที่เปลี่ยนแปลง(ค่าเบี่ยงเบนมาตรฐาน)ในกลุ่มควบคุมเท่ากับ19.25(15.9) และในกลุ่มทดลองเท่ากับ 25.25(16.68) ซึ่งไม่มีความแตกต่างกันทางสถิติที่p-value 0.067 และ ร้อยละ95ของช่วงความเชื่อมั่นของผลต่างเฉลี่ยเท่ากับ 6.0(-0.42 – 12.43) ผู้เข้าร่วมวิจัยทั้ง 2 กลุ่มรู้สึกว่าอาการปวดหลังโดยภาพรวมดีขึ้น ร้อยละ 89 และ ร้อยละ90ของทั้ง 2 กลุ่มพึงพอใจกับการใช้เครื่องดึงหลัง

สรุปผลการศึกษา จากข้อมูลที่ได้จากการวิจัย ไม่สามารถแสดงให้เห็นประสิทธิผลของการใช้เครื่องดึงหลังในผู้ป่วยที่มีอาการจากภาวะหมอนรองกระดูกเคลื่อนเฉียบพลัน

ลายมือชื่อนิสิต.....

สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่ออาจารย์ที่ปรึกษา.....

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Keywords :ACUTE HERNIATED DISC SYNDROME/ LUMBAR TRACTION/ EFFECTIVENESS/ RANDOMIZED CONTROLL TRIAL

NOPAWAN SANJAROENSUTTIKUL: EFFECTIVENESS OF LUMBAR TRACTION WITH ROUTINE CONSERVATIVE TREATMENT IN ACUTE HERNIATED DISC SYNDROME.

THESIS ADVISOR; ASSIST.PROF. MANATHIP OSIRI, THESIS CO-ADVISOR; ASSOC.PROF. KINGKAEW PAJAREYA 68 PAGES. ISBN : 974-17-4445-5

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 4 th week of the treatment. At the end of 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.

Student's signature……

Field of study Health Development Advisor's signature……

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LIST OF ABBREVIATION

AHCPR	Agency for health care policy and research
CI	Confidence Interval
HNP	herniated nucleus pulposus
LBP	low back pain
NSAIDs	Non-steroid anti-inflammatory drugs
Osw score	Oswestry low back pain score
RCTs	Randomized Controlled trials
SD	Standard Deviation
SLRT	straight leg raising test

CHAPTER 1

Background and rationale

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, with 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]

Low back pain may originate from several spinal structures, including ligaments, facet joints, vertebral periosteum, paravertebral musculature and fascia, annulus fibrosus and spinal nerve roots. The most common causes are musculoligamentous injuries and age-related degenerative processes in the intervertebral disc and facet joints. Approximately 85 % of patients with isolated low back pain cannot be given a precise pathoanatomical diagnosis. The association between symptoms and imaging results is weak.[3]

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

For patients with 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.[8-11] 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.[12, 13]One of the treatment options is traction, which can be combined with other techniques, such as massage exercise, electrotherapy 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.[14, 15] 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 blinded assessor.[16] 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.[16]

CHAPTER 2

Literature review

Disc herniation is defined as abnormal rupture or protrusion of nucleus pulposus exerting outward of annulus fibrosus. It is a common cause of acute, chronic or recurrent low back pain.[17]

Disc herniation most commonly occurs at the L4 – 5 or L5 – S1 level.[17]

Only 1 – 11 %of disc herniation originate from the L1-2, L2-3 or L3-4 level.[18, 19]Risk factors include mechanical strain on the spine from heavy lifting, repetitive lifting, twisting and vibration.[20]

The AHCPR clinical practice guideline define acute low-back problems as

" The activity intolerance due to lower back or back-related leg symptoms of less than 3 months' duration".[21]

Clinical feature

Medical history

Sciatic pain was defined by O'Connell in 1943 as pain along the course and in the distribution of sciatic nerve, pain radiating to the posterior thigh and below the knee to the foot in the L5 or S1 dermatome.[4]

The leg pain of sciatica is often associated with numbness or paresthesia. Moreover sciatica due to disc herniation typically increases with cough, sneezing or performance of the valsalva maneuver.[3]

Physical examination

SLRT should be performed in patients with sciatica. The patient's heel is supported with the examiner's one hand while the other hand is placed over the same limb's patella.[22] The leg is slowly elevated as the examiner keeps the patient's leg straight. A positive test reproduces the symptoms of sciatica, with pain that radiates below knee, not merely back or hamstring pain. The elevation of less than 60 degrees is abnormal, suggesting compression or irritation of nerve roots.

Although the SLRT is considered an important clinical test for lumbar intervertebral disc herniation,[23-25] there are many variation such as: how it should be carried out, the mechanism of its limitation, and its clinical significance.

Most authors had suggested that compression of the nerve root was the most likely cause of pain during the SLRT.[26, 27] The sciatic nerve root, being relatively fixed between the dura and the intervertebral foramen, was unable to move away from the disc protrusion and the compression and SLRT induced traction generated pain.[28]

The effect of the SLRT on sciatic nerve had been observed under the in vitro conditions at the nerve is exit from pelvis after only 1 or 2 inches of leg raise and is noticeable at the intervetebral foramen after 20° to 30° of elevation. The motion was greatest at 60° to 80° of SLRT.[29]

Other pain-producing mechanisms being proposed included damage to related ligamentous structures and collateral creation of inflammatory focus over the dural cuff of the nerve, nerve root edema,[28] nerve root irritation[29] and intervertebral foramen venous obstruction.[30]

Thelander et al[25] found no correlation between the protrusion size, shape or location and SLRT restriction. Instead they ascribed the reproduced pain was caused by inflammatory reaction in the dural sheet. In addition, they noted that any decrease in protrusion size which might have occurred over time was not accompanied by improvement in SLRT response.

According to the studies that used operative findings as the gold standard, the pooled sensitivity of SLRT was high (0.91; 95%CI 0.78-0.97) and the specificity was 0.32 (95%CI 0.17 – 1.52).[31] Whereas sensitivity and specificity of cross-SLRT was 0.32 (95%CI 0.16 – 0.54) and 0.98 (95%CI 0.94 – 0.99), respectively.[32] Besides SLRT, other physical signs such as paresis, sensory deficits and depressed reflexes were nonsensitive and nonspecific.[31, 33]

Diagnostic Studies

Most patients with acute low back pain can be improved with conservative management so they usually do not require immediate diagnostic studies.[34]

Plain radiography has a limited role in diagnosis of disc herniation while the accuracy of MRI, myelography and myelography with CT scan is 96%, 81% and 84% respectively.[35] Intervertebral disc abnormalities diagnosed from CT[36-38] and MRI[38] have shown poor correlation with the symptoms.

MRI scan does not show correlation with back pain in relation to disc bulging and protrusion. However, severe disc protrusion or extrusion is rarely found in asymptomatic individuals, and neural compromise is the best predictor of symptomatic disc protrusion.

Disc bulge is found in 25% of the 20- to 30- year old asymptomatic individuals and in 60% of the 40- to 50- year old ones, and disc protrusion is found in 20 and 30%, respectively.[39, 40]

The correlation between the morphologic changes in HNP and the symptom improvement was still controversial. The main reasons were the difficulty in the follow up of asymptomatic patients and the lack of the proper and noninvasive methods to investigate morphologic changes.[41]

A number of studies have shown that the morphologic changes on MRI corresponded to clinical outcomes. The improvement in radicular pain may result from decreased pressure on symptomatic nerve root or subsided inflammation around nerve root without morphologic changes[42] or the inability of MRI to detect a small decrease that might allow the improvement of radicular pain.

Many authors have described several hypotheses on the mechanisms of HNP disappearance, i,e, retraction by posterior longitudinal ligament tension, dehydration, disc degeneration, resorption by macrophage phagocytosis, and immunologic reaction.[43-45]

Clinicians should consider a diagnostic reevaluation that may include special imagings if the patients'activity continues to be limited by their back symptoms for more than 1 month without improvement. For patients whose activity is limited by sciatica for more than 4 weeks with physiologic evidence of neurologic dysfunction, MRI or CT is an appropriate consideration to provide anatomic definition of suspected herniated disc before surgery.[21]

Natural history

Acute LBP has a favorable prognosis – the 2000UK-guideline state that 90% (of cases) will recover within six weeks.[46] Pain decreased rapidly between 12 – 84% of initial level (mean 58%) within one month. Pain continued to decrease more slowly, until about 3 months. A similar trend was seen for disability, which decreased by between 33 – 83 % of initial levels (mean 58 %) within one month.[47]

The natural history of herniated disc is also benign. Improvement is slower than improvement in LBP alone. Only about 10 percent of patients have sufficient pain after six weeks that surgery is considered.[43, 48]

In patients with sciatica, both leg and back pain decreased by 69 % of initial scores within one month. Disability decreased by 57 % of initial scores within one month. By the end of first year, some 30% still complained of back pain, decreased working ability and limitation in recreational activities. Data of long-term pain and disability were not available.[49]

Treatment

In the absence of the cauda equina syndrome or progressive neurologic deficit, patient with suspected disc herniation should be treated nonsurgically for at least a month.[3] The presence of mild or moderate motor deficit does not necessarily affect the indication for surgery or conservative treatment.[50]

In the majority of patients, conservative treatment relieves pain in a few days to several months. Resolution of symptoms may occur in the presence of herniation of any type or size.[50]

To date, there have been many therapeutic interventions for conservative treatment, this review focused only on traction, NSAIDs, activity modification, exercise and short-term bed rest of stay active.

Traction

Traction can improve the signs and symptoms of acute LBP by both biomechanical effects such as separation of the intervertebral motion segment[51] and neurophysiological effects, such as modulation of nociception input.[52]

Effect of traction

1. Normalization of neurological deficit and relief of radicular pain.

   Mechanical compromise is possibly associated with abnormalities such as intervertebral disc lesions, which cause ischemia or inflammation of spinal nerve or dorsal root ganglion or nerve root complex.[53]These pathological changes which accompany neurological deficit could theoretically be relieved by traction. The separation of the vertebrae helps relieve radicular pain and normalize neurological deficits by relieving direct pressure or contact force in sensitized neural tissues.[51, 54]

2. Reduction of intervertebral disc protrusion

   The evidence for this hypothesis is unclear. Mathews[55] injected contrast medium into lumbar spine and took radiography before, during and after spinal traction. Disc protrusions were reduced during application, however, after the release of traction force, the protrusions reappeared although not to the original size. Design problems of this study were the lack of control group, lack of accuracy of radiographic measurements and failure to correlate observed changes in disc contours with signs and symptoms.

3. Improvement in the SLRT

Traction has also been shown to improve painfully restricted SLR, probably by increasing the diameter of the intervertebral foramina, thus decompressing neural tissue and reducing neural sensitivity to movement. Inflammation of neural tissues has been correlated with decreased range of motion of SLR.[56]

NSAIDs

NSAIDs are the mainstay of pharmacologic therapy in LBP. Guidelines for the management of LBP in primary care have been published in the United States[21], the United Kingdom,[57] New Zealand and the Netherlands. All of these guidelines recommend the prescription of NSAIDs as one option for symptomatic relief in the early management of acute LBP.

A systematic review on the efficacy of NSAIDs for LBP suggest that NSAIDs are slightly effective for short-term global improvement in patients with acute LBP. NSAIDs are more effective than bed rest, but not more effective than other analgesic drugs, physiotherapy or spinal manipulation of acute LBP. There is strong evidence that various types of NSAIDs are equally effective for acute LBP.[58]

Henry et al [59]reported the results from a meta-analysis on serious gastrointestinal complications from the use of NSAIDs. They concluded that ibuprofen was associated with the lowest risk of serious gastrointestinal complications. If no medical contraindication is present, a two to four-week course of medication at antiinflammatory levels is suggested.[34]

Activity modification

Activity modification is now the preferred recommendation for back pain patients. The patient should avoid painful arcs of motion and tasks that exacerbate the back pain such as bending at the waist, lifting and prolonged sitting or standing.[4]

Exercise

The current results show that exercise therapy is not more effective than inactive treatments or other active treatments for acute low back pain. [60] The evidence showed that flexion and extension exercises are not effective in the treatment of acute low back pain. [60] Exercise therapy was more effective than usual care by the general practitioner and just as effective as conventional physiotherapy (consisting of hot pack, massage, traction, mobilization, short-wave diathermy, ultrasound, electrotherapy) for chronic low back pain[60].

Exercise may be useful within an active rehabilitation program if they facilitate ordinary activity and return to work. Specific back exercises have no clinical effect.[60]

Short-term bed rest or stay active

Restricted activity, rest, bed rest and symptomatic treatment with analgesics are most commonly treatment for low back pain and sciatica.[61] Care during the acute stage consists mainly of passive methods. However, prolonged inactivity, like bed rest, leads to the deterioration of many body functions, and may therefore inhibit improvement of low back pain.[62] Clinical practice guidelines recommend early activity in the management of acute low back pain.[21] Waddell et al[63] recommended early stay active, because it resulted in faster return to work, less chronic disability, and fewer recurrent problems.

Advice to stay active as single intervention, compared with bed rest or exercise, may have little beneficial effect for patients with acute simple low back pain, and may not be better or worse than prolonged bed rest for patients with sciatica. There is no evidence that advice to stay active is harmful for either acute low back pain or sciatica. Then it is reasonable to advice people with acute low back pain and sciatica to stay active.[64]

Treatment outcome

Oswestry low back pain disability questionnaire is commonly recommended as a condition specific outcome measure for spinal disorders.[65] John O'Brien developed the Oswestry questionnaire in 1976. Patients with chronic low back pain completed the questionnaire and give a percentage score of their level of functions. The questionnaire selected from a series of experimental questionnaires designed to assess limitations of various activities of daily living. The Oswestry questionnaire is an effective method of measuring disability in patients with back pain with a wide degree of severity and causes.[68]

The discussion groups in 1991 and 1992 reviewed the available outcome measures for patients with back pain. Both groups concluded that the Oswestry questionnaire was reasonably confined to disability according to the WHO definition. The Oswestry questionnaire focused on physical activities but not the psychological consequences of acute or chronic pain. Its internal consistency showed acceptable degree with the Cronbach's alpha of 0.70 – 0.87.[66]

Meade[67] chose 4 points as the minimum difference in mean scores between the two groups that showed clinical significance. The US Food and Drug Administration has chosen a minimum 15 points change in patients who undergo spinal fusion before surgery

and at follow up. Estimated population means of Oswestry score change for different spinal diseases and changes after treatment are consistent with clinical experience.

The Oswestry questionnaire was originally published in English and translated into nine other languages.

Oswestry questionnaire consists of 10 questions explored the pain in daily function (see appendix2&3). It is a self-administered questionnaire, which avoids interviewer bias. In addition, it can be administered by telephone interviewing but the complexity of the response items may make it not suitable for the interviewing.

CHAPTER 3

Research Methodology

Research questions

Primary research question

Do the patient receive lumbar traction have different mean of the Oswestry low back pain disability score changed more than 8 [69] from those who receive routine conservative treatment?

Secondary research questions

1. Is the patient's global improvement (patient 's point of views) in both groups different from each other ?
2. Is the satisfaction of the patients who received lumbar traction different from those who receive routine conservative treatment?
3. Is the number of total tablet usage of NSAIDs in both groups different from each other?
4. What are the adverse effects of lumbar traction?

Objectives

Primary objective

To compare the effectiveness of the treatment by lumbar traction with the routine conservative treatment of acute herniated disc syndrome in term of pain reduction and functional recovery measured by the change of the Oswestry low back pain disability score.

Secondary objectives

1. To compare the global improvement of the patients with acute herniated disc syndrome in both groups.
2. To compare the patient's satisfaction in both groups.
3. To compare the number of total tablet usage of NSAIDs in both groups.
4. To evaluate the adverse effects of lumbar traction.

Hypothesis

Research hypothesis

The patient with acute herniated disc syndrome who received lumbar traction had different change in mean of Oswestry low back pain disability score from those who received routine conservative treatment.

Statistical hypothesis

Null hypothesis Ho : $\mu_L = \mu_C$

Alternative hypothesis Hi : $\mu_L \neq \mu_C$

Where μ_L : mean change of the Oswestry low back pain disability score in a patient received lumbar traction

μ_C : mean change of the Oswestry low back pain disability score in a patient received routine conservative treatment

Conceptual framework

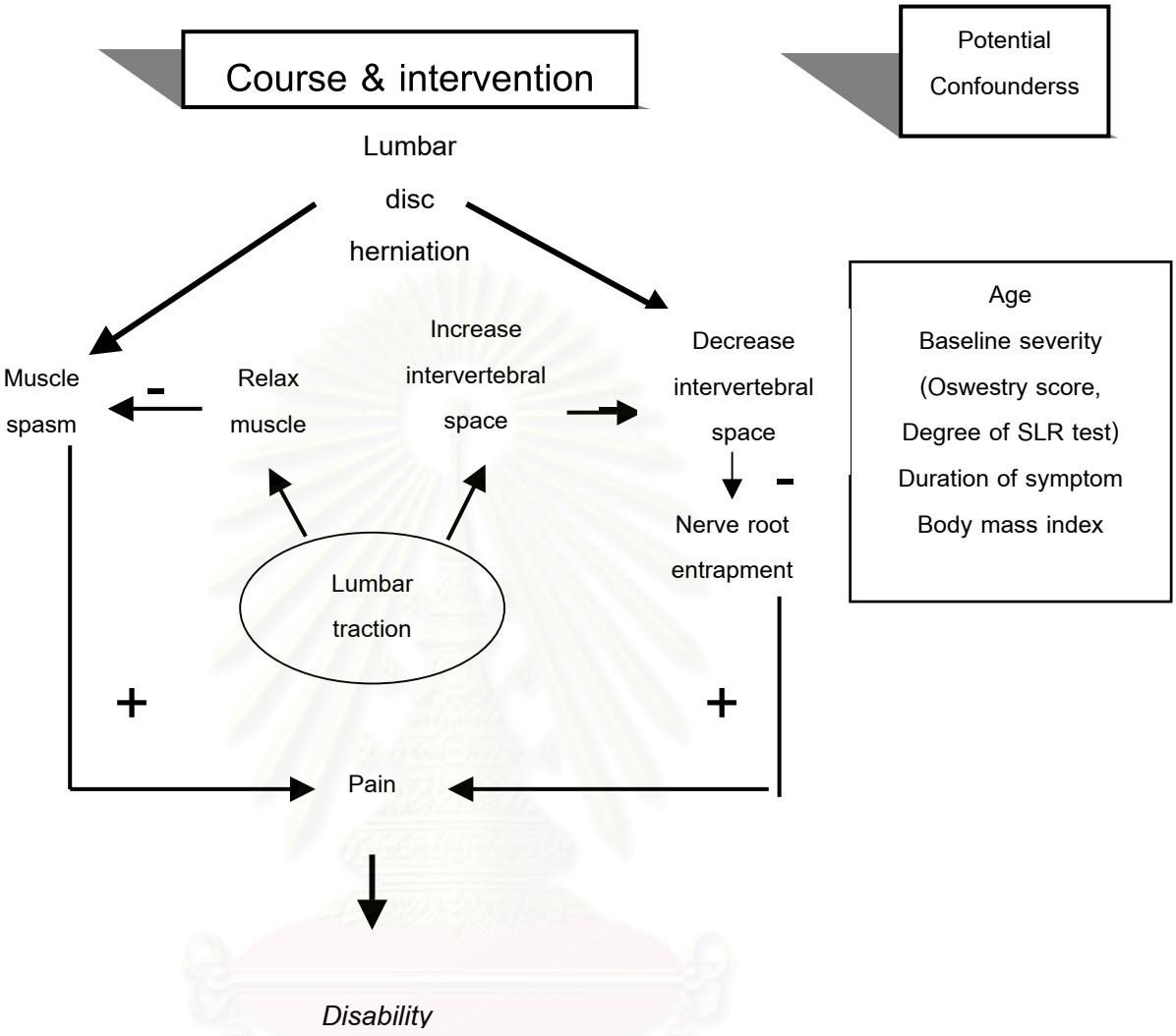


Figure 3.1 : Conceptual framework

Keywords

Acute herniated disc syndrome, Lumbar traction, Effectiveness, Randomized controlled trial

Operational definition

Diagnostic criteria: The diagnosis of acute herniated disc syndrome were based on the history of low back pain for less than 3 months[21] 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]
2. Physical examination revealed positive tension signs test such as sciatica stretch test (SLRT).
3. MRI or myelogram showed evidence of lumbar disc bulging or protrusion.[35]

Research design

Prospective, randomized controlled trial, double-blinded.

Population and Sample

Population

Target population: The patient with acute herniated disc syndrome

Study population: All of the patients who met the diagnostic criteria of acute herniated disc syndrome at 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 this study.

Inclusion criteria

- Meet the diagnostic criteria of acute herniated disc syndrome.
- Age more than 18 years old, both sex
- Suffered from acute low back pain with or without radiating pain for less than 3 months
- Baseline Oswestry score range from 20-80
- Signed informed consent

Exclusion criteria

- 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
- Evidence of underlying disease with anatomical abnormalities such as rheumatic disease, spondyloarthropathy
- Progressive neurological deficit

Sample collection

The numbers of participants are recorded from Pranangklao Hospital, Sirindhorn National Medical Rehabilitation Centre, King Chulalongkorn Memorial Hospital and Ramathibodi Hospital were 45, 10, 10 and 55 respectively.

Sample size calculation

Calculation of the sample size is based on the type of primary outcome measurement. Since this study compares mean change from baseline of Oswestry score : The following formula for comparing of the two independent means is used.

$$n \text{ / group} = \frac{2\sigma^2[Z_\alpha + Z_\beta]^2}{(\mu_C - \mu_L)^2}$$

where α = type 1 error = .05 (2 sided) , $Z_\alpha = 1.96$

β = type 2 error = .20 , $Z_\beta = 0.84$ (power of test 80%)

μ_C = mean change from baseline of Oswestry low back pain disability score in control group

μ_L = mean change from baseline of Oswestry low back pain disability score in intervention group

σ = standard deviation of change in Oswestry score for control and intervention groups

From literature review, the difference of mean change between the two groups which showed clinical significance was 8,[69] the standard deviation of the change in score of the two groups was 14. For 2 sided α of 0.05, power of study is 80 %. so number of patients per group is equal to

$$n = \frac{2(14)^2(1.96+0.84)^2}{8^2}$$

Sample size in each group will be 48.

Assume 20% drop out rate, the sample size per group will be = $\frac{48}{(1 - 0.2)}$

Sample size in each group will be 60. Finally total sample size equal 120

Randomization

By simple randomization using random number tables, sealed in envelopes. After the participants signed inform consent. They met the physiotherapist, who knows the random list.

Intervention

Control group : Patients receive routine conservative treatments (consisting of NSAIDs, appropriate position and activity for back protection , back exercise, heat) plus sham traction (placebo).

Intervention group : Patients receive routine conservative treatment plus lumbar traction.

All patients receive lumbar traction under supervision of one physiotherapist. The setting of traction is intermittent hold for 45 seconds, then rest for 30 seconds. The patients' position is 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, which the patient would feel a little pulling from harness. For each session, the physiotherapist will record the date,

applied duration, force of traction and complication if occurred. Patients attend as OPD case for 3 times per week and 20 minutes per session.

All patients will receive the NSAIDs, booklet-containing advice on the appropriate activity for protection of the back pain, back exercise (such as back mobilization, flexion and extension exercises) and home used superficial heat. They will be ask to record daily use of NSAIDs, heat and back exercise.

The intervention would be terminated if the patients have progressive neurological deficit, aggravation of pain or as patient's request. Then they have to complete the Oswestry questionnaire and record the reason of termination.

Measurement

1. Demographic data : name, occupation
2. Baseline variables : age, gender, baseline of Oswestry score, degree of straight – leg raising (SLRT), history of pain radiating below knee, body mass index, number of previous low back pain episode.
3. Primary outcome variables : Change of score Oswestry low back pain disability questionnaire.

   All subjects had to complete this questionnaire, right after signed inform consent and at 4th week after the intervention. The changes of score will be calculated from the values at baseline and at 4 th week.

4. Secondary outcome variables:

   4.1 Global improvement

   Recorded at the end of study by the patients using six-level categorical scale "complete recovery, much improve, little improve, not change, little worse, and much worse ".

   4.2 Patient's satisfaction

   Recorded at the end of the study on four-level categorical scale " very satisfied, moderately satisfied, unsatisfied, and very unsatisfied ".

   4.3 Adverse effects of lumbar traction

   The physiotherapist asked the patient for any pain or respiratory constrain occurred during the traction program.

Co – intervention

1. NSAIDs usage

   All patients will take full dose of NSAIDs for 2weeks, and then as necessary for pain relief.

   All patients will take the same kind of NSAIDs and record total pill usage.

2. Application of heat

   The recommendation for home used superficial heat is 20 minutes per session. Duration and frequency of heat application per day is recorded.

3. Back exercise

   The main purpose of back exercise was to promote early mobility.
   The patient will be instructed to perform back exercise with 40 repetitions per day and record the number of the exercise session.

   All patients have to report any additional treatment for pain relief.

Contamination

The physiotherapist will record the loading weight usage in lumbar traction for individual patient.

All patients were asked for not to have lumbar traction from other hospital or clinic.

Compliance

Traction application

The compliance of traction application divide into 3 categories.

1. Good defines as the patient receives total traction of 9 – 12 times.

2. Fair defines as the patient receives total traction of 6 – 8 times.

3. Poor defines as the patient receive total traction of 1- 5 times.

Back exercise performance

Good defines as the patient is able to complete 40 repetitions set of back exercise per day for 21 –28 days, fair :14 – 20 days and poor : 1 – 13 days.

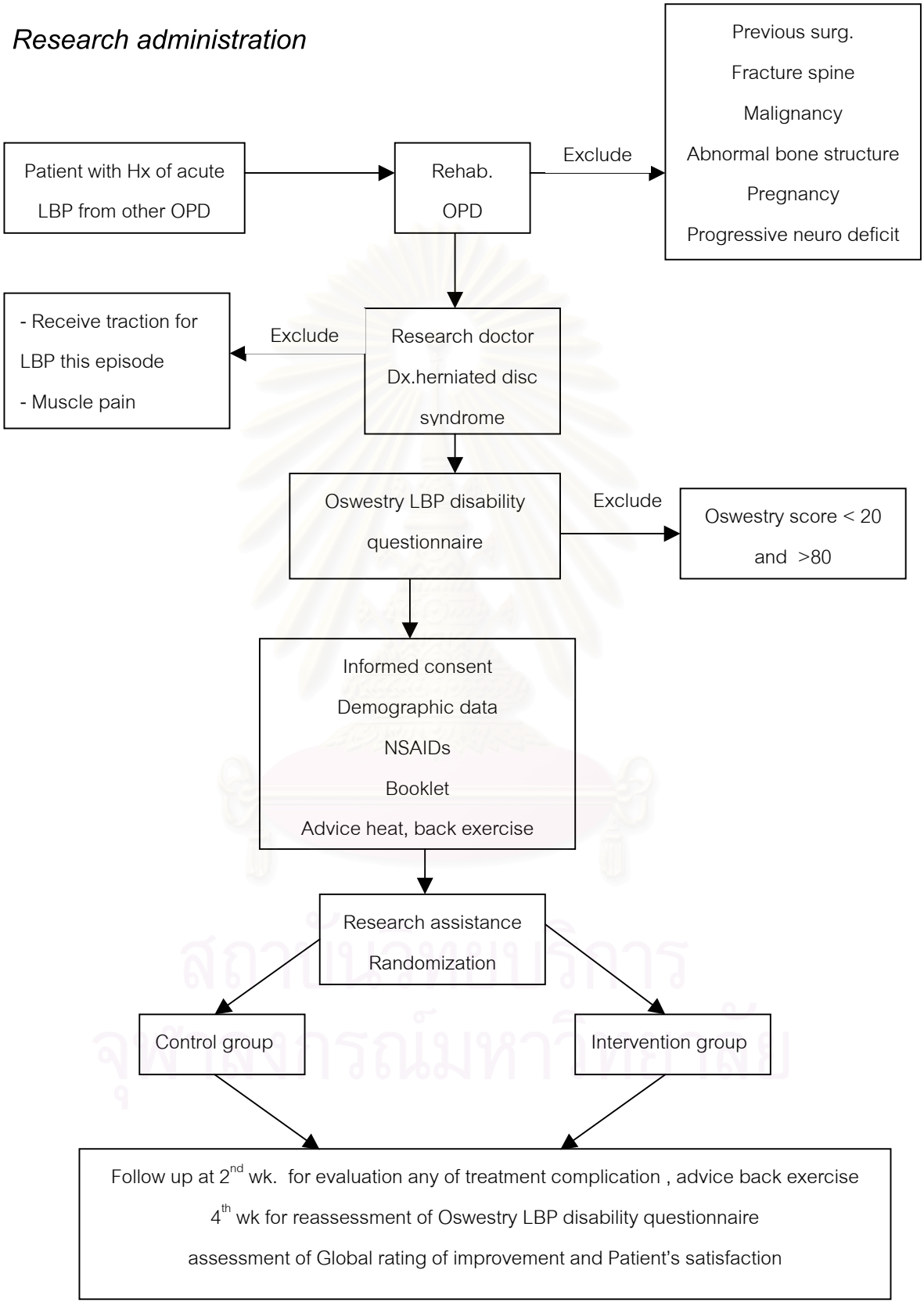


Figure 3.2 Research administration

Data analysis

Demographic and baseline data

variable	Type of variable	Statistic
- Age (years)	Ratio	Mean , SD
- Gender (male / female)	Nominal	Frequency
- Straight – leg raising (degree)	ordinal	Frequency
- Oswestry LBP disability score	Ratio	Mean , SD
- Pain radiating below knee (yes / no)	Nominal	Frequency
- Body mass index	Ratio	Mean , SD
- Previous LBP (number)	Ordinal	Frequency

The baseline data will be analyzed by descriptive statistics. Gender, straight – leg raising and history of pain radiating below knee and number of previous LBP episode will be described in frequency of distribution. The continuous data will be tested for normal distribution. The mean (SD) or median (IQR) is used for describing data as appropriate.

Outcome variables

Variable	Type of variable	Statistic
Primary outcome Oswestry LBP disability score in 0 ,4th wk.) Change of score from baseline between 2 groups	ratio	Mean ,SD Unpaired t – test
Secondary outcome Global improvement Patient 's satisfaction Adverse effect (y/n)	 ordinal ordinal nominal	 Chi-square for trend Chi-square for trend Frequency

The Oswestry score will be tested for normal distribution using one sample Kolmorogov-Smirnov.

Unpaired t-test will be used to compare Oswestry score change between the two groups.

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

The adverse effects will be present in frequency distribution

Co-intervention

Variable	Type of variable	Statistic
NSAIDs	Ratio	Unpaired t-test
Heat	Ratio	Mann-Whitney U test
Back excercise	ordinal	Chi-square test

The heat and NSAIDs usage will be tested for normal distribution. Then unpaired t-test or nonparametric test was used to compare between the two groups.

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

Ethical Consideration

1. The research proposal was submitted to and approved by the Hospital Ethics Committee.
2. All patients received the information related to the study before being asked to sign the consent form. The information includes the details of intervention and adverse effect.
3. The patients are aware of their right to withdraw from the study at any time without the interference with their regular care.
4. The adverse effect of lumbar traction is the heavy weight of traction and respiratory constraints due to traction harness. We minimized these adverse effect by using specially trained physiotherapist and close monitoring of the patients during the application of traction.

Limitation

1. It is impossible to blind the physiotherapist regarding the type of intervention.
2. The drop out rate may high because the inconvenient of the patient to receive lumbar traction at hospital. This may not detect the difference between the two groups.
3. The sample size may be larger than the number of patient of OPD rehabilitation and requires extratime to recruit enough patients to the study.

Expected benefit of the study

If the result of this study does not favor the traction, the prescription of this intervention is not recommended in clinical practice. The patient will need only home program. This will reduce the costs and time loss for the patients. On the other hand, if the result does support the efficacy of this intervention, lumbar traction will be another important tool for the treatment of lumbar herniated disc syndrome and should be recommended in all patients without contraindication.

CHAPTER 4

Results

Demographic and baseline data

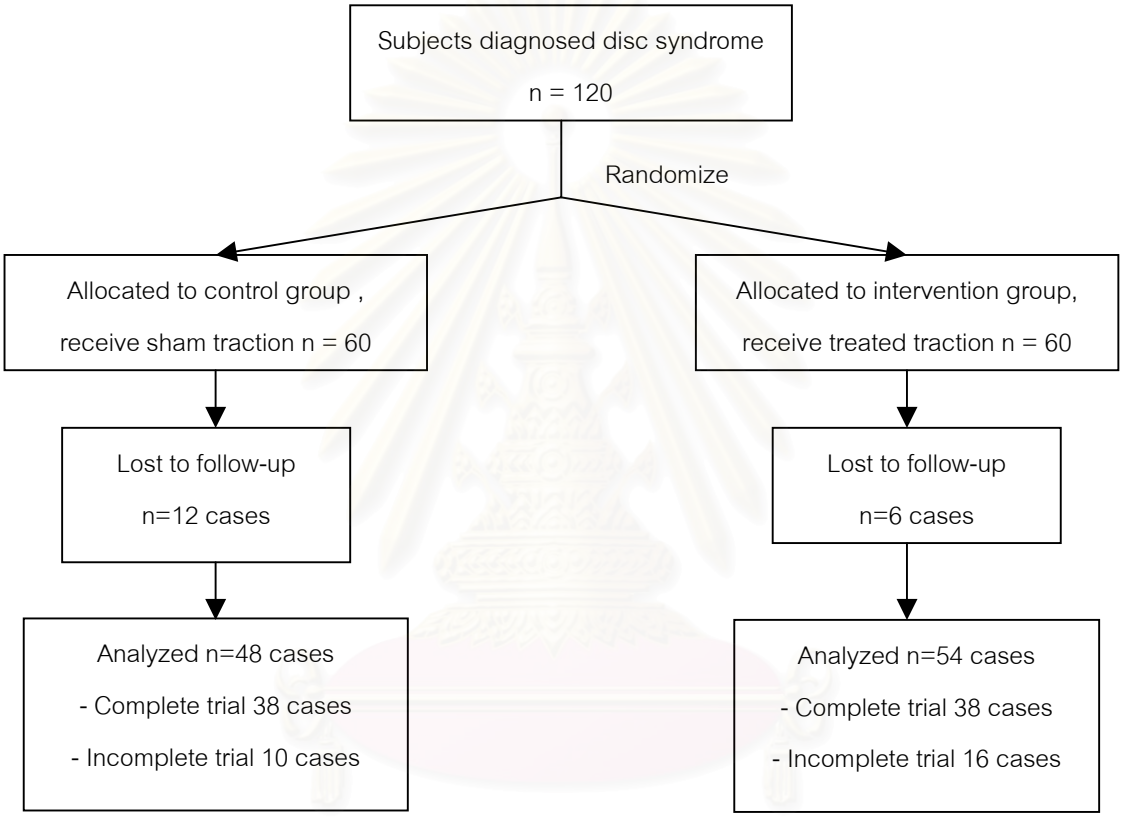
One hundred and twenty participants diagnosed of lumbar disc syndrome, who met the criteria were enrolled into the study between March 2003 – January 2004 at the outpatient clinic, Department of Physical Medicine and Rehabilitation of 4 institutes (Pranangklao Hospital, Sirindhorn National Medical Rehabilitation Centre, King Chulalongkorn Memorial Hospital and Ramathibodi Hospital). Some data collected from each institute represents in table4.1. The majority of cases collected from Ramathibodi Hospital and Pranangklao Hospital. The Oswestry score at baseline in intervention group had higher than control group in all institutes except Chulalongkorn Hospital.

Table 4.1 Data collected from each institute.

Institues	No. of patient	No.of intervention : control	No. of drop out	Mean Oswestry score (SD) at baseline	
				Intervention	Control
Rama	55	26:29	11	44.17 (14.65)	41.90 (14.37)
Pranangklao	45	25:20	6	52.95 (16.18)	42.07 (12.07)
Sirindhorn	10	4:6	1	55.11 (16.21)	46.76 (11.22)
Chula	10	5:5	0	39.95 (12.34)	41.04 (18.11)

The 120 cases were allocated to the intervention and control groups. The subjects' progresses through the phase of randomized trial were demonstrated in figure4.1.

Figure 4.1 : Flow diagram of subject progress through the phase of randomized trial



Baseline characteristics of both groups were comparable regarding gender, age, number of previous LBP episode, history of radiating pain, degree of SLRT, present mild neurological deficit, and body mass index. The baseline Oswestry score of both groups had normal distribution, tested using one sample Kolmorogov-Smirnov. Unpaired t-test was used; the score had statistically significant difference between the two groups at p-value 0.023. (Table4.2)

Table4.2: Baseline characteristics of all patients

Characteristics	Control group	Intervention group	P - value
No. of patients	60	60	
Gender ; Male (%)	32(53.3%)	27(45.0%)	
Female(%)	28(46.7%)	33(55.0%)	
Mean age (years)(SD)	37.08 (8.01)	37.00 (7.99)	
History of pain radiating (%)			
- No	7(11.7%)	2(3.3%)	
- Radiate below knee	45(75.0%)	46(76.7%)	
- Radiate above knee	8(13.3%)	12(20.0%)	
No. of previous LBP episode(%)			0.492
- First attack	24(40.0%)	30(50.0%)	
- 1 – 5	27(45.0%)	21(35.0%)	
- 6 – 10	9(15.0%)	9(15.0%)	
Degree of SLRT(%)			0.195
- negative	31(51.7%)	20(33.3%)	
- 30	5(8.3%)	10(16.7%)	
- 45	8(13.3%)	10(16.7%)	
- 60	16(26.7%)	20(33.3%)	
Present of mild neurodeficit (%)			
- Weak EHL	11(18.3%)	9(15.0%)	0.624
- Decreased ankle jerk	1(1.7%)	3(5.0%)	0.619
Mean body mass index (SD)	23.23 (3.67)	23.42(3.98)	0.785
Mean baseline Osw score(SD)	42.27 (13.50)	48.46 (15.76)	0.023
(min – max)	(20 – 73.33)	(20 –80)	

EHL ; extensor hallusis longus

At the end of study, the numbers of drop out in the control and the intervention groups were 12 and 6 cases, respectively. The baseline characteristics of drop out group are shown in Table4. 3.

Table 4.3: Baseline characteristics of the drop-out patients

Characteristics	Control group	Intervention group
No. of patients	12	6
Gender ; Male	6	6
Female	6	0
Mean age (years)(SD)	38.58 (9.64)	29.50 (6.86)
No. of previous LBP episode		
- First attack	4	3
- 1 – 5	5	2
- 6 – 10	3	1
History of pain radiating		
- Radiate below knee	9	3
- Radiate above knee / no	3	3
Degree of SLRT		
- negative	7	1
- 30	1	1
- 45	2	2
- 60	2	2
Presenting mild neurodeficit		
- Weak EHL	1	1
- Decrease ankle jerk	0	0
Mean body mass index (SD)	24.47 (4.82)	21.59(3.09)
Mean baseline Osw score(SD)	48.94 (9.55)	52.85 (20.4)
(min – max)	(28.89-60.00)	(26.00-80.00)

EHL ; extensor hallusis longus

After exclude dropout patients, the baseline data of the remaining patient were analyzed and presented in Table4.4

Table4.4 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 knee	36(75.0%)	43(79.6%)	
- Radiate above knee	7(14.6%)	9(16.7%)	
No. of previous LBP episode(%)			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%)	
Present 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)	

EHL ; extensor hallusis longus

Outcome analysis

The Oswestry score

The Oswestry score were obtained at baseline and at 4th week. The Oswestry score in each section shown in Table 4.5 represented mean (SD) at baseline and at 4th week of control and intervention groups. Patients in both groups had high mean score of pain, lifting, sitting and standing. In intervention group had higher mean score in walking, social life and travelling. After 4th week, the patients in both groups had decreased Oswestry score in all activities and total scores.

Table 4.5 : Compare Oswestry score in each section

	Control group (n = 48)		Intervention group. (n = 54)	
	Baseline Osw	Osw 4 thwk	Baseline Osw	Osw 4 thwk
Pain	3.08(1.29)	1.23(1.53)	3.11(1.21)	1.13(1.57)
Personal care	1.42(0.79)	0.42(0.74)	1.48(0.86)	0.37(0.78)
Lifting	2.90(1.40)	2.44(1.69)	3.43(1.28)	2.50(1.74)
Walking	1.88(1.02)	1.02(1.02)	2.30(1.08)	1.00(1.03)
Sitting	1.98(1.12)	0.94(0.95)	2.37(1.26)	0.93(0.97)
Standing	2.00(1.37)	1.19(1.25)	2.57(1.25)	1.41(1.33)
Sleeping	1.50(1.62)	0.52(1.01)	1.65(1.39)	0.52(1.08)
Sex life	1.67(1.65)	0.68(1.07)	1.64(1.55)	0.96(1.20)
Social life	1.77(1.34)	1.02(1.26)	2.70(1.49)	1.31(1.53)
Travelling	1.60(1.23)	0.88(1.04)	2.20(1.63)	1.04(1.41)
Total score	40.61(13.94)	21.36(17.27)	47.97(15.32)	22.74(18.64)

Primary outcome analysis

Table 4.6 shows results of the Oswestry score in both groups. The change of Oswestry score of each subject was calculated. The raw score of changes of both groups were tested for normal distribution with one sample Kolmorogov-Smirnov. They had normal distribution. Unpaired t - test was used to compare the difference in the change of the Oswestry score. 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 were no statistically significant in means change of the Oswestry score between these two groups (6.0 ; 95%CI -0.42 ,12.43; p = 0.067).

Table 4.6: 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)	6.0 (-0.42 –12.43)	0.067

Secondary outcome analysis

The data of global improvement and satisfaction of both groups were presented in number and percentage in Table 4.7.

Table 4.7: Results of global improvement and satisfaction

	Control group (n=48)	Intervention group (n=54)
Global improvement (%)		
- Complete recovery	9(18.8%)	9(16.7%)
- Much improve	25(52.1%)	29(53.7%)
- Little improve	9(18.8%)	10(18.5%)
- Not change	3(6.2%)	4(7.4%)
- Little worse	2(4.2%)	0
- Much worse	0	2(3.7%)
Satisfaction (%)		
- Very satisfied	30(68.2%)	34(66.7%)
- Moderately satisfied	10(22.7%)	14(27.5%)
- Unsatisfied	3(6.8%)	3(5.9%)
- Very unsatisfied	1(2.3%)	0

For global improvement, about 50% in each group had significant improvement of their symptoms. There were 10.5% in the control and 11.1% in the intervention groups rated themselves as unchanged and worsened of their symptoms.

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

The Chi-square for trend was tested for compare difference of global improvement and satisfaction between two groups. The adapted data were present in Table 4.8. In this adapted data showed no statistically significant difference on global improvement and satisfaction between the two groups.(P-value > 0.05)

Table 4.8: 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 improve	25(52.1%)	29(53.7%)	
- Little improve / Not change	12(25.0%)	14(25.9%)	
- Little / Much worse	2(4.2%)	2(3.7%)	
Satisfaction (%)			0.895
- Very satisfied	30(68.2%)	34(66.7%)	
- Moderately satisfied	10(22.7%)	14(27.5%)	
- Unsatisfied / Very unsatisfied	4(9.1%)	3(5.9%)	

Compliance and adverse effect of traction

In Table 4.9, there were 38 patients in each group received full course for traction. The Chi – square test showed no statistically significant difference between the two groups. Pain was observed in 4 patients treated with traction and 2 patients in the control group.

Table 4.9 : Compliance and adverse effect of traction

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

Co-intervention

Table 4.10 presents the co-interventions consisting of heat, NSAIDs usage and back exercise. The frequency home used heat and numbers of total tablet usage of NSAIDs in both groups were tested for their distribution with one sample Kolmorogov – Smirnov. The distribution of frequency home used heat was not normal. The Mann-Whitney-U test was used to compare heat usage between the two groups. Unpaired t-test was used to compare numbers of total tablet usage of NSAIDs between both groups. 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 Chi-square test was used to compare days of complete set of back exercise in both groups. The data had to be adapted by combination of data of patient in good and fair into one group, who performed exercise more than 14 days per course. The adapted data of back exercise is presented in Table 4.11.

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

Table4.10: 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)	0.893*
Mean NSAIDs tablets used (SD) (min – max)	53.77 (24.26) (0- 84)	50.78 (24.79) (4-84)	0.54
Back exercise performance(%)			
- Good (21-28 days/course)	2(4.2%)	3(5.6%)	
- Fair (14 –20days/course)	8(16.7%)	3(5.6%)	
- Poor (less than 13 days/course)	38(79.2%)	48(88.69%)	

* not normally distributed, statistic test by Mann-Whitney U-test

Table 4.11: Co-intervention : back exercise.

	Control group (n=48)	Intervention group (n=54)	P - value
Back exercise performance (%)			0.178
- Perform exercise≥14 days/course (good & fair)	10(20.8%)	6(11.1%)	
- Perform exercise <14 days/course (poor)	38(79.2%)	48(88.9%)	

CHAPTER 5

Discussion

Study design

This study was designed to overcome flaw methodological quality of RCTs described in systematic review of traction. From systematic review there were several pitfalls in the randomization, sample size calculation, incomparable of co-intervention, blinding of both patient - assessor, measurement and standardization of interventions.

The following described the detail of this study that overcome pitfalls.

1. Insufficient description of randomization

   This study used simple randomization with random number tables, sealed in envelopes.

2. Small sample size.

   The sample size calculation of this study according to the difference of mean change from baseline of the Oswestry score between the two groups to demonstrate the difference of 8 on the Oswestry score that shows clinical significance, with a power of 80% and alpha of 0.05, assuming a standard deviation of 14 for both groups. In this study, the difference of with SD 15 and $n_1 = 48$, $n_2 = 54$, giving a power of study about 46.3%

3. Co-intervention

   The co-intervention prescribe in two groups consisting of home used heat, NSAIDs and back exercise according to AHCPR clinical practice guidelines.

4. Blinding

The blinding process had been done for both patients and assessor. However, it was impossible to blind the physiotherapist regarding the type of intervention.

5. Measurement

The Oswestry score was the standard tool used for assessing the primary outcome. The Thai version of the Oswestry questionnaire was tested for validity and reliability before applied in this study. Content validity and Cronbach's alpha was acceptable.(see appendix 1)

6. Standardized of intervention

The intervention procedures were standardized for weight and position. Since the weight and position during apply the traction had effect to the spine. The setting of traction in this study provided the greatest vertebral separation.

Patients who suffered from acute low back pain and met the diagnostic criteria for acute herniated disc were recruited for this study. Since there has been no physical examination or radiography did not correlate with the symptoms, the diagnostic criteria described in the operational definition was then used to recruit and classify these patients as having disc syndrome.

Results

The demographic data of gender, age, frequency of previous LBP, history of radiating pain, degree of SLRT, present of mild neurodeficit and body mass index were similar in both groups. The drop out rate was about 15% (12 and 6 cases in control and intervention groups respectively). The reason of this group of patients that cannot come to be follow up may be due to most of them were labor worker who were paid on a daily basis. When they had 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 in effectiveness of treatment is occupation. Patient have to had some adaptation in workplace to help back protect, but I lack this data.

The Oswestry scores after treatment were improved over time in both groups. By statistic 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 unequal number of patients collection in each institute that lead to unproportion severity distribution of patients difference in each hospital and unequal distribution of sampling selection by sealed envelopes. The other reason might be effect from wide range of the Oswestry score.

To minimize the effect of 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 statistic 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 is statistical test. ANCOVA (one-way analysis of covariance) was used to adjust the baseline difference of the Oswestry score. It showed no statistic difference in mean change of the Oswestry score between 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 outlier in 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 full course (good compliance) of traction. If only good compliance group were analyzed, there still no statistical difference between the two groups with p-value 0.116. Regarding the adverse effect of traction was minimal in both groups.

Eighty-nine percentages of patients in each group had improvement of symptoms. Two patients in intervention group had much worse symptom. One patient goes back home in rural area, rest for 4 weeks and received only one time treatment. Another patient had decreased pain in the second week but she got severe cough for a few days before follow up at 4 th week. And 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 overall of the 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 seem to be unnecessary. Since the effective of traction cannot prove. Patient can receive conservative treatment as a home program and this will safe cost and time.

Suggestion.

In my opinion, future research on traction therapy should not receive high priority.

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APPENDICES

Appendix 1 :Measurement

Oswestry low back pain disability questionnaire was initiated by John O'Brien in 1976 to identify the disturbance of activities of daily living in patients with low back pain.

The questionnaire is categorized into ten sections

1. Pain intensity
2. Personal care
3. Lifting
4. Walking
5. Sitting
6. Standing
7. Sleeping
8. Sex life
9. Social life
10. Traveling

The questionnaire can be completed in less than 5 minutes and scored in less than 1 minute.

<u>Scoring system</u>

For each section of 6 statements the total score is 5 ; the first statement is marked score=0, the last statement is marked score=5. If more than one box is marked in each section, take the highest score. If all 10 sections are completed the score is calculated as follows:

if total score = 16 out of 50x100 = 32%

if one section is missed : 16 out of 45 x 100 = 35.6%

The disability score was interpreted into 0 – 100. The higher score indicated the worse function in common activities of daily living.

This questionnaire was translated into Thai version by 2 translators who work in the physical medicine and rehabilitation field. Both translators had adapted some statements such as

- In section 4 – walking : To fit for Thai, the distance “mile” unit had to changed to “ kilometer” and how many bus stop they can walk without pain. One bus stop distance equal to 300 - 400 meters.
- In section 9 – social life : It shows examples of social life activities such as go shopping, sport or theater.

  And the back translation was performed by a language professional, which was accepted.

Validity and reliability test

1. Validity measurement

1.1 Face and content validity

This kind of validity measures whether the scale appears to be assessing the desired qualities. The Thai version of this questionnaire was sent to 5 experts in physical medicine and rehabilitation field. All experts evaluate the qualities in aspect of relevance and appropriateness for Thai culture.

The scoring system is as followed

+1 for relatively valid item

0 for not sure

−1 for relatively irrelevant item

The score were calculated by using this formula

$$IC = \frac{\Sigma R}{N}$$

Where IC = item correlation

R = total score of that item

N = number of experts

TableA.1 : Results of the content validity testing

expert / Item	1	2	3	4	5	IC
1	1	1	1	-1	1	0.6
2	1	1	1	1	1	1
3	1	0	1	1	1	0.8
4	1	0	1	0	1	0.6
5	1	1	1	1	1	1
6	1	1	1	1	1	1
7	1	0	1	1	1	0.8
8	1	1	1	-1	1	0.6
9	0	1	1	0	1	0.6
10	1	1	1	1	1	1

From the above formula : item correlation of each item ranged from 0.6 – 1.This indicated that the Thai version Oswestry questionnaire was qualified (item correlation of each item should be more than 0.5).

1.2 Construct validity

This means the extent to which a measure is related to specified variables in accordance with an established theory or ‘ hypothetical construct”

The Oswesty questionnaire assesses pain in daily activities. Pain is an abstract variable that cannot be directly observed. In original version, the wording of the Oswestry questionnaire was designed on the basis of patients’ self-report and symptoms of chronic low back pain. Many studies of the Oswestry questionnaire have shown its validity. Firstly, it shows moderate correlation with pain measures (VAS & McGill Pain Questionnaire) and quality of life measure (SF-36). Secondly, it has been used to validate the pain disability index, the low back outcome score, the Manniche scale, the Aberdeen score and a functional capacity evaluation.

1.3 Criterion validity

This validity is the correlation of a scale with some other measure, ideally, a” gold standard” which has been used and accepted in the field. But now there has never been any gold standard to measure the pain level. So the Oswestry questionnaire can’t be assessed in criterion validity.

2. Reliability measurement

Before one can obtain evidence that the instrument is measuring, it is necessary to gather evidence that the scale is measuring something in reproducible fashion. Ways in which reliability measures can be obtained

2.1 Internal consistency

The questionnaire was completed by 32 patients, who complained of acute low back pain (less than 3 months). The data were then calculated for Cronbach’s alpha using SPSS program version 11.0

Table A.2 : The item-total statistics of the Oswestry questionnaire

Item	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Alpha If Item Deleted
Pain	17.2813	81.2409	.2701	.7391
Personal care	19.0000	80.0645	.4596	.7151
Lifting	17.5938	79.6683	.4615	.7284
Walking	18.2813	80.2732	.5604	.7164
Sitting	18.1250	79.1452	.5958	.7184
Standing	18.3438	76.5554	.5606	.7016
Sleeping	19.0000	82.0000	.3205	.7257
Sex life	15.7188	56.4022	.4549	.7879
Social life	18.0313	74.3538	.3421	.7153
Travelling	18.6250	77.2097	.6286	.7054

Standardized item alpha = 0.8107

The Cronbach's alpha of all items was 0.8107 that indicate a good reliability. (Internal consistency should exceed 0.8)

2.2. Stability is a way of examining the reproducibility of measure.

In the original study, the patients with chronic low back pain were tested twice at 24 hour interval (r= 0.99). This may include a memory effect. If the test - retest interval is extended to 4 days, the correlation of scores decrease to r = 0.91 and, if retest after a week, r = 0.83. The disadvantage of increasing the time interval is that natural symptom fluctuation may also be an influence factor.

Because of the fluctuation of acute pain occurred intermittently over time, the Thai version Oswestry questionnaire had not been performed for test – retest reliability.

Appendix 2 :Oswestry low back pain disability questionnaire (Original version)

This questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage in every day life. Please answer every section, and mark in each section only the one box which applies to you. We realize you may consider that two of the statements in any one section relate to you, but please just mark the box which most closely describes your problem.

Section1 Pain intensity

☐ I can tolerate the pain I have without having to use painkillers.

☐ The pain is bad but I manage without taking painkillers.

☐ Painkillers give complete relief from pain.

☐ Painkillers give moderate relief from pain.

☐ Painkillers give very little relief from pain.

☐ Painkillers have no effect on the pain and I do not use them.

Section 2 Personal care (washing, dressing, etc.)

☐ I can look after myself normally without causing extra pain.

☐ I can look after myself normally but it causes extra pain.

☐ It is painful to look after myself and I am slow and careful.

☐ I need some help but manage most of my personal care.

☐ I need help every day in most aspects of self-care.

☐ I do not get dressed, wash with difficulty and stay in bed.

Section 3 Lifting

☐ I can lift heavy weights without extra pain.

☐ I can lift heavy weights but it gives extra pain.

☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g. on a table.

☐ Pain prevents me from lifting heavy weights off the floor, but I can manage light to medium weights if they are conveniently positioned.

☐ I can lift only very light weights.

☐ I cannot lift or carry anything at all.

Section 4 Walking

☐ Pain does not prevent my walking any distance.

☐ Pain prevents me walking more than 1 mile.

☐ Pain prevents me walking more than ½ mile.

☐ Pain prevents me walking more than ¼ mile.

☐ I can only walk using a stick or crutches.

☐ I am in bed most of the time and have to crawl to the toilet.

Section 5 Sitting

☐ I can sit in any chair as long as I like.

☐ I can sit in my favorite chair as long as I like.

☐ Pain prevents me sitting more than 1 hour.

☐ Pain prevents me from sitting more than ½ an hour.

☐ Pain prevents me from sitting more than 10 minutes.

☐ Pain prevents me from sitting at all.

Section 6 Standing

☐ I can stand as long as I want without extra pain.

☐ I can stand as long as I want but it gives me extra pain.

☐ Pain prevents me from standing for more than 1 hour.

☐ Pain prevents me from standing for more than 30 minutes.

☐ Pain prevents me from standing for more than 10 minutes.

☐ Pain prevents me from standing at all.

Section 7 Sleeping

☐ Pain does not prevent me from sleeping well.

☐ I can sleep well only by using tablets.

☐ Even when I take tablets I have less than 6 hours sleep.

☐ Even when I take tablets I have less than 4 hours sleep.

☐ Even when I take tablets I have less than 2 hours sleep.

☐ Pain prevents me from sleeping at all.

Section 8 Sex life

☐ My sex life is normal and causes no extra pain.

☐ My sex life is normal but causes some extra pain.

☐ My sex life is nearly normal but is very painful.

☐ My sex life is severely restricted by pain.

☐ My sex life is nearly absent because of pain.

☐ Pain prevents any sex life at all.

Section 9 Social life

☐ My social life is normal and gives me no extra pain.

☐ My social life is normal but increases the degree of pain.

☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. dancing, etc.

☐ Pain has restricted my social life and I do not go out as often.

☐ Pain has restricted social life to my home.

☐ I have no social life because of pain.

Section 10 Travelling

☐ I can travel anywhere without extra pain.

☐ I can travel anywhere but it gives me extra pain.

☐ Pain is bad but I manage journeys over two hours.

☐ Pain restricts me to journeys of less than one hour.

☐ Pain restricts me to short necessary journeys under 30 minutes.

☐ Pain prevents travel except to the doctor or hospital.

Appendix 3: Thai version Oswestry questionnaire

แบบสอบถามสำหรับผู้ป่วยที่มีปัญหาเรื่องปวดหลัง *ID……..*

1. ชื่อ ……. นามสกุล…….HN…….
   ที่อยู่ที่ติดต่อได้ ……
   เบอร์โทรศัพท์ ……..
2. อายุ ……..ปี เพศ □ ชาย □ หญิง
3. อาชีพ ……
4. ท่านมีปัญหาปวดหลังเป็นเวลานาน …… ปี …….เดือน ……..สัปดาห์ …….วัน
5. ท่านมีปัญหาปวดขาเป็นเวลานาน ……...ปี …….เดือน ……..สัปดาห์ …….วัน

คำชี้แจง

แบบสอบถามนี้จัดทำขึ้นเพื่อแพทย์ได้รับทราบข้อมูลเกี่ยวกับอาการปวดหลังของท่านที่มีผลในการดำเนินชีวิตประจำวัน

กรุณาตอบแบบสอบถามทุกข้อโดยทำเครื่องหมาย √ ลงใน □ เพียงช่องเดียวที่สามารถอธิบายอาการได้ใกล้เคียงกับอาการของท่านมากที่สุด

1. ความรุนแรงของอาการปวด
   □ อาการปวดของฉันพอทนได้โดยไม่ต้องใช้ยา
   □ อาการปวดของฉันแย่มาก แต่ฉันก็จัดการได้โดยไม่ต้องใช้ยา
   □ ยาแก้ปวดช่วยลดอาการปวดได้ทั้งหมด
   □ ยาแก้ปวดช่วยลดอาการปวดได้บางส่วน (ประมาณครึ่งหนึ่ง)
   □ ยาแก้ปวดช่วยลดอาการปวดได้เล็กน้อย
   □ ยาแก้ปวดไม่ช่วยลดอาการปวดและฉันไม่ได้ใช้ยาแก้ปวดนั้น

2. การดูแลตัวเองในชีวิตประจำวัน (อาบน้ำ , แต่งตัว เป็นต้น)
   □ ฉันสามารถอาบน้ำ , แต่งตัว ได้เหมือนปกติโดยไม่ทำให้อาการปวดมากขึ้น
   □ ฉันสามารถอาบน้ำ , แต่งตัว ได้เหมือนปกติแต่ทำให้มีอาการปวดเกิดขึ้น
   □ ฉันสามารถอาบน้ำ , แต่งตัว ได้แต่ต้องเป็นไปอย่างช้า ๆ และระมัดระวัง เพราะ ทำให้มีอาการปวด
   □ ฉันสามารถอาบน้ำ , แต่งตัว ได้แต่ต้องมีผู้ช่วยเหลือบ้างบางส่วน
   □ ฉันสามารถอาบน้ำ , แต่งตัว ได้แต่ต้องมีผู้ช่วยเหลือเกือบทั้งหมด
   □ ฉันไม่สามารถอาบน้ำ , แต่งตัว ได้เอง และต้องอยู่แต่บนเตียง

3. การยกของ

☐ ฉันสามารถยกของหนักได้โดยไม่มีอาการปวดมากขึ้น

☐ ฉันสามารถยกของหนักได้แต่ทำให้เกิดอาการปวดมากขึ้น

☐ ฉันไม่สามารถยกของหนักจากพื้นได้ แต่ถ้าของหนักอยู่สูงระดับโต๊ะ ฉันจะสามารถยกของหนักนั้นได้

☐ ฉันไม่สามารถยกของหนักจากพื้นได้ แต่ถ้าของหนักอยู่สูงระดับโต๊ะ ฉันจะสามารถยกของได้แต่น้ำหนักของต้องไม่มากนัก

☐ ฉันสามารถยกได้แต่ของน้ำหนักเบา ๆ

☐ ฉันไม่สามารถยกของได้เลย

4. การเดิน

☐ ฉันสามารถเดินได้ระยะทางเหมือนปกติโดยไม่มีอาการปวด

☐ อาการปวดทำให้ฉันสามารถเดินได้ระยะทางไม่เกิน 1.6 กิโลเมตร(ประมาณ 5 ป้ายรถเมล์)

☐ อาการปวดทำให้ฉันสามารถเดินได้ระยะทางไม่เกิน 800 เมตร(ประมาณ 2 ป้ายรถเมล์)

☐ อาการปวดทำให้ฉันสามารถเดินได้ระยะทางไม่เกิน 400 เมตร(ประมาณ 1 ป้ายรถเมล์)

☐ ฉันสามารถเดินได้แต่ต้องใช้เครื่องช่วยเดิน เช่น ไม้เท้า , ไม้ค้ำพยุง

☐ ฉันต้องอยู่แต่บนเตียง แต่ต้องคลานเวลาจะไปห้องน้ำ

5. การนั่ง

☐ ฉันสามารถนั่งได้นานเหมือนปกติโดยไม่มีอาการปวด

☐ ฉันสามารถนั่งได้นานเหมือนปกติโดยไม่มีอาการปวดเฉพาะเก้าอี้ที่ฉันนั่งเป็นประจำ และสบายเท่านั้น

☐ อาการปวดทำให้ฉันสามารถนั่งได้ไม่เกิน 1 ชั่วโมง

☐ อาการปวดทำให้ฉันสามารถนั่งได้ไม่เกิน 30 นาที

☐ อาการปวดทำให้ฉันสามารถนั่งได้ไม่เกิน 10 นาที

☐ อาการปวดทำให้ฉันไม่สามารถนั่งได้เลย

6. การยืน

☐ ฉันสามารถยืนได้นานเหมือนปกติ โดยไม่มีอาการปวดมากขึ้น

☐ ฉันสามารถยืนได้นานเหมือนปกติแต่จะทำให้ฉันปวดมากขึ้น

☐ อาการปวดทำให้ฉันสามารถยืนได้ไม่เกิน 1 ชั่วโมง

☐ อาการปวดทำให้ฉันสามารถยืนได้ไม่เกิน 30 นาที

☐ อาการปวดทำให้ฉันสามารถยืนได้ไม่เกิน 10 นาที

☐ อาการปวดทำให้ฉันไม่สามารถยืนได้เลย

7. การนอน

☐ ฉันสามารถหลับได้เหมือนปกติ โดยไม่มีอาการปวด

☐ ฉันสามารถหลับได้เหมือนปกติแต่ต้องใช้ยา

☐ ถึงแม้จะใช้ยาแล้วก็ตามฉันสามารถหลับได้น้อยกว่า 6 ชั่วโมง

☐ ถึงแม้จะใช้ยาแล้วก็ตามฉันสามารถหลับได้น้อยกว่า 4 ชั่วโมง

☐ ถึงแม้จะใช้ยาแล้วก็ตามฉันสามารถหลับได้น้อยกว่า 2 ชั่วโมง

☐ อาการปวดทำให้ฉันไม่สามารถหลับได้เลย

8. การมีเพศสัมพันธ์

☐ ฉันสามารถมีเพศสัมพันธ์ได้เหมือนปกติโดยไม่มีอาการปวดมากขึ้น

☐ ฉันสามารถมีเพศสัมพันธ์ได้เหมือนปกติแต่จะทำให้ฉันปวดมากขึ้น

☐ ฉันสามารถมีเพศสัมพันธ์ได้เกือบเหมือนปกติ แต่มีอาการปวดมาก

☐ ฉันมีเพศสัมพันธ์ได้น้อยมากเพราะอาการปวด

☐ ฉันปวดมากจนแทบจะไม่สามารถมีเพศสัมพันธ์ได้

☐ ฉันปวดมากจนไม่สามารถมีเพศสัมพันธ์ได้เลย

9. การเข้าสังคม เช่น การไปตลาด ดูหนัง ไปห้างสรรพสินค้า

☐ ฉันสามารถเข้าสังคมได้เหมือนปกติโดยไม่มีอาการปวดมากขึ้น

☐ ฉันสามารถเข้าสังคมได้เหมือนปกติโดยมีอาการปวดมากขึ้น

☐ อาการปวดไม่ได้มีผลต่อการเข้าสังคมของฉันมากนักยกเว้นมีกิจกรรมที่ต้องเคลื่อนไหวมาก เช่น การเต้นรำ เล่นกีฬา เป็นต้น

☐ อาการปวดทำให้ฉันไม่สามารถเข้าสังคมนอกบ้านได้บ่อย ๆ

☐ อาการปวดทำให้ฉันไม่สามารถเข้าสังคมนอกบ้านได้แต่สามารถมีการเข้าสังคมที่จัดในบ้านได้

☐ อาการปวดทำให้ฉันไม่สามารถเข้าสังคมได้เลย

10. การเดินทาง

☐ ฉันสามารถเดินทางไปที่ต่าง ๆ ได้โดยไม่มีอาการปวดมากขึ้น

☐ ฉันสามารถเดินทางไปที่ต่าง ๆ ได้แต่มีอาการปวดมากขึ้น

☐ อาการปวดของฉันแย่มาก แต่ฉันก็สามารถจัดการได้ และเดินทางได้มากกว่า 1 ชั่วโมง

☐ อาการปวดทำให้ฉันสามารถเดินทางไปที่ต่าง ๆ ได้น้อยกว่า 1 ชั่วโมง

☐ อาการปวดทำให้ฉันสามารถเดินทางไปที่ใกล้ ๆ ได้ที่ใช้เวลาน้อยกว่า 30 นาที

☐ ฉันไม่สามารถเดินทางไปที่ต่าง ๆ ได้ ยกเว้นไปพบแพทย์ หรือ ไปโรงพยาบาล

Appendix 4: Case record form

Patient 's name ..... HN..... ID.....

Selection of subjects

Inclusion criteria	Yes	No
1. Age more than 18 years old	☐	☐
2. History of acute low back pain less than 6 weeks	☐	☐
and 2.1 History of back pain had worsen by coughing sneezing, straining or present with sciatica pain	☐	☐
or 2.2 Physical examination reveal positive tension signs test such as SLRT, femoral nerve stretch test	☐	☐
or 2.3 MRI or myelogram show evidence of lumbar disc bulging or protrusion	☐	☐
3. Baseline Oswestry score range 20 – 80	☐	☐
4. Inform consent	☐	☐

Exclusion criteria

- Receive lumbar traction for acute low back pain problem in this episode.	☐	☐
- Previous surgery for low back pain problem	☐	☐
- Suspected malignancy	☐	☐
- Pregnancy	☐	☐
- Fracture of lumbar spine	☐	☐

- Evidence underlying disease or anatomical abnormalities such as rheumatic disease, SNSA (seronegative spondyloarthropathy) ☐ ☐
- Progressive neurological deficit ☐ ☐

Baseline data

1. Age …….. years old
2. Sex ☐ male ☐ female
3. Weight …….. Kg

   Height …….. Cm

   Body mass index (BMI) ……
4. Duration of this acute low back pain …….. weeks …… days
5. Number of previous low back pain episode ……
6. History of pain radiating below knee ☐ yes ☐ no
7. Degree of SLRT ……..
8. Baseline Oswestry score ……..

Outcome measurement

1. Follow up Oswestry score ……
2. Global improvement

   ☐ complete recovery ☐ much improve ☐ little improve

   ☐ not change ☐ little worse ☐ much worse

3. Patient ‘s satisfaction

☐ very satisfy ☐ mederately satisfy ☐ unsatisfied ☐ very unsatisfied

4. Adverse effect

☐ yes ,specify ☐ respiratory constraint

☐ pain

☐ other

☐ no

Compliance

1. NSAIDs usage

Total pill use …….

2. Heat application

Number appropriation use of heat (per day)…….

3. Back exercise

☐ too much ☐ appropriate ☐ less

4. Traction

Total number of receive traction ……..

☐ Good compliance (9 – 12 times/treatment)

☐ Fair compliance (6 – 9 times / treatment)

☐ Poor compliance (1 – 5 times / treatment)

Appendix 5 Patient information sheet

เอกสารชี้แจงข้อมูล / คำแนะนำผู้เข้าร่วมโครงการ

ชื่อโครงการวิจัย การศึกษาประสิทธิผลของการใช้เครื่องดึงหลังกับการรักษาแบบไม่ผ่าตัดในผู้ป่วยที่มีอาการจากภาวะ หมอนรองกระดูกเคลื่อนเฉียบพลัน

ชื่อผู้วิจัย พญ.นพวรรณ แสนเจริญสุทธิกุล

สถานที่วิจัย แผนกเวชศาสตร์ฟื้นฟู

การติดต่อเมื่อมีเหตุฉุกเฉิน พญ.นพวรรณ แสนเจริญสุทธิกุล

เบอร์โทรศัพท์ 02-2011154, 02-6923871 กด 1

ผู้สนับสนุนการวิจัย คณะแพทยศาสตร์ รพ.รามาธิบดี

ความเป็นมาของโครงการ

อาการปวดหลังเป็นปัญหาที่พบบ่อย ซึ่งอาการปวดหลังที่เกิดจากภาวะหมอนรองกระดูกเคลื่อนเป็นสาเหตุที่ทำให้เกิดภาวะปวดหลังเรื้อรังและพิการได้

การรักษาอาการปวดหลังมีทั้งการรักษาแบบผ่าตัด และแบบไม่ผ่าตัด ซึ่งการรักษาโดยการใช้เครื่องมือทางกายภาพบำบัดที่นิยม คือ การใช้เครื่องดึงหลัง ซึ่งจากการศึกษาที่ผ่าน ๆ มา ยังไม่มีข้อมูลชัดเจนเกี่ยวกับประสิทธิผลของการใช้เครื่องดึงหลังในผู้ป่วยภาวะหมอนรองกระดูกเคลื่อน

วัตถุประสงค์

เพื่อเปรียบเทียบประสิทธิผลการรักษาโดยการใช้เครื่องดึงหลังร่วมกับการรักษาแบบไม่ผ่าตัดสำหรับผู้ป่วยที่มีภาวะหมอนรองกระดูกเคลื่อนเฉียบพลัน เทียบกับ กลุ่มผู้ป่วยที่ได้รับการรักษาแบบไม่ผ่าตัดอย่างเดียว

รายละเอียดที่จะปฏิบัติต่อผู้เข้าร่วมวิจัย

ท่านจะได้รับทราบข้อมูลซึ่งประกอบด้วย รายละเอียดของการศึกษา การสุ่มเข้ารับการรักษาโดยการใช้เครื่องดึงหลังซึ่งแบ่งเป็น 2 กลุ่ม (กลุ่มที่หนึ่งจะใช้น้ำหนักในการดึงหลังไม่เกิน 20%ของน้ำหนักตัวซึ่งจะไม่มีผลต่อหมอนรองกระดูก และอีกกลุ่มจะใช้น้ำหนักในการดึงหลัง35-50%ของน้ำหนักตัว) รวมทั้งภาวะแทรกซ้อนที่อาจเกิดขึ้นจากการใช้เครื่องดึงหลังท่านจะลงนามยินยอมเข้าร่วมทำการศึกษาวิจัยท่านจะถูกบันทึกข้อมูลทั่วไป กรอกแบบสอบถาม และรับคำแนะนำเกี่ยวกับการดูแลอาการปวดหลังท่านจะถูกสุ่มเข้ารับการรักษาวิธีใดวิธีหนึ่งโดยต้องมาทำ

กายภาพบำบัดใช้เครื่องดึงหลัง 3 ครั้งต่อสัปดาห์ เป็นเวลาติดต่อกัน 4 สัปดาห์ และผู้ป่วยจะพบแพทย์ในสัปดาห์ที่ 2 และสัปดาห์ที่ 4 เพื่อประเมินการรักษาเป็นระยะๆ ท่านสามารถขอออกจากการศึกษาได้ โดยจะไม่มีผลต่อการรักษาที่จะได้รับต่อไป

ประโยชน์และผลข้างเคียงที่จะเกิดขึ้น

ข้อมูลที่ได้จากการวิจัยจะช่วยเป็นแนวทางในการให้การรักษาผู้ป่วยที่มีภาวะหมอนรองกระดูกเคลื่อน เฉียบพลันได้อย่างเหมาะสมต่อไป

ผลข้างเคียงที่อาจเกิดขึ้น อาจทำให้ท่านรู้สึกอึดอัด อันเนื่องมาจากสายรัดรอบเอวของเครื่องดึงหลัง ดังนั้นนักกายภาพบำบัดจะเป็นผู้ดูแล และเฝ้าระวังในระหว่างการใช้เครื่องดึงหลัง

การเก็บข้อมูลเป็นความลับ

ข้อมูลทั้งหมดจะถูกเก็บเป็นรหัส ซึ่งสามารถค้นข้อมูลย้อนกลับได้ โดยข้อมูลทั้งหมดจะเก็บไว้ที่ผู้วิจัย เพียงผู้เดียว

ถ้าท่านมีปัญหาข้องใจหรือรู้สึกกังวลใจกับการเข้าร่วมในโครงการวิจัยนี้ ท่านสามารถติดต่อกับประธานกรรมการจริยธรรมการวิจัยในคน คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี โทร. 0-2201-1541 ในเวลาราชการ

Appendix 6 Informed Consent Form

หนังสือยินยอมโดยได้รับการบอกกล่าวและเต็มใจ

ชื่อโครงการ : การศึกษาประสิทธิผลของการใช้เครื่องดึงหลังกับการรักษาแบบไม่ผ่าตัดในผู้ป่วยที่มีอาการจากภาวะ หมอนรองกระดูกเคลื่อนเฉียบพลัน

ชื่อผู้วิจัย : พญ.นพวรรณ แสนเจริญสุทธิกุล

ชื่อผู้ถูกทำวิจัย……

อายุ……**เลขที่เวชระเบียน**……..

คำยินยอมของผู้ถูกทำวิจัย

ข้าพเจ้า นาย/นาง/นางสาว……ได้ทราบรายละเอียดของโครงการวิจัยตลอดจนประโยชน์ และข้อเสี่ยงที่จะเกิดขึ้นต่อผู้ยินยอมตนให้ทำวิจัยจากผู้วิจัยแล้วอย่างชัดเจน ไม่มีสิ่งใดปิดบัง ซ่อนเร้นและยินยอมให้ทำการวิจัยในโครงการที่มีชื่อข้างต้น และข้าพเจ้ารู้ว่าถ้ามีปัญหาหรือข้อสงสัยเกิดขึ้น ข้าพเจ้าสามารถสอบถามผู้วิจัยได้ และข้าพเจ้าสามารถไม่เข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบต่อการรักษาที่ข้าพเจ้าพึงได้รับ นอกจากนี้ผู้วิจัยจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่าง ๆ ที่เกี่ยวข้องกระทำได้ เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ลงชื่อ……(ผู้ยินยอมตนให้ทำวิจัย)

……..(พยาน)

……..(พยาน)

วันที่ ……

คำอธิบายของแพทย์หรือผู้วิจัย

ข้าพเจ้าได้อธิบายรายละเอียดของโครงการ ตลอดจนประโยชน์ของการวิจัย รวมทั้งข้อเสี่ยงที่อาจจะเกิดขึ้น แก่ผู้ยินยอมตนให้ทำวิจัยทราบแล้วอย่างชัดเจนโดยไม่มีสิ่งใดปิดบังซ่อนเร้น

ลงชื่อ……(แพทย์หรือผู้วิจัย)

วันที่……

หมายเหตุ : กรณีผู้ยินยอมตนให้ทำวิจัยไม่สามารถอ่านหนังสือได้ ให้ผู้วิจัยอ่านข้อความในใบยินยอมฯ นี้ให้แก่ผู้ยินยอมตนให้ทำวิจัยฟังจนเข้าใจดีแล้วและให้ผู้ยินยอมตนให้ทำวิจัยลงนามหรือพิมพ์ลายนิ้วหัวแม่มือรับทราบในการให้ความยินยอมดังกล่าวข้างต้นไว้ด้วย

CURRICULUM VITAE

Nopawan Sanjaroensuttikul,MD. was born on August 4, 1970 in Bangkok. She was graduated from Faculty of Medicine Ramathibodi hospital. She is a certified Thai Board of Physical Medicine and Rehabilitation. She has been working as an attending instructor at the Department of Physical Medicine and Rehabilitation Ramathibodi hospital since 1999.

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