·临床研究·

A comparison between multi-directional mechanical traction and longitudinal traction for treatment of lumbar disc herniation: a randomized clinical trial with parallel-group design*

ZHANG Yang[1] YUE Shouwei[1,2] WANG Yanqin[1]

Abstract

Objective: To evaluate the clinical effectiveness of multi-directional mechanical traction (MT) for the treatment of patients with lumbar disc herniation (LDH) compared with longitudinal traction (LT) as control.

Method: This prospective, single-blind, randomized clinical trial was performed in Qi Lu Hospital, Shandong University from January 2008 to December 2008. One hundred and twenty outpatients with LDH were randomly divided into MT group or LT group. MT group was treated with computer-controlled multi-directional mechanical traction. LT group was treated with longitudinal traction. Roland Morris Low Back Pain and Disability Questionnaire (RMDQ), visual analogue scale (VAS), and straight leg raising (SLR) angle were measured for every patient pre-, 4 weeks post-, and 1 year post-treatment.

Result: The results of clinical observations showed significant improvements in RMDQ, VAS, and SLR angle assessments (all $P<0.05$) in both groups 4 weeks post- and 1 year post-treatment compared with pre-treatment. Score of RMDQ in MT group was significantly lower than that in LT group($P<0.05$), however, there was no significant difference between two groups in VAS score and SLR angle ($P>0.05$). The differences in improvement ratios between two groups were not significant (all $P>0.05$). The clinical outcomes were negatively correlated with patient's age and disease duration.

Conclusion: The effect of MT is equivalent and probably superior to that of LT in improving the symptoms and clinical findings of patients with LDH.

Key word treatment outcome; traction; lumbar disc herniation; pain; physical therapy

腰椎多方位快速牵引与腰椎纵向牵引临床疗效的对比研究/张杨，岳寿伟，王艳琴//中国康复医学杂志，2011，26(7)：638—643

目的：本研究的目的是通过与腰椎纵向牵引比较，评价多方位快速牵引的临床疗效。

方法：本研究为前瞻性随机对照研究。120例确诊为腰椎间盘突出症的患者被随机分为2组，分别进行多方位快速牵引和纵向牵引的治疗，在治疗前、治疗后4周和1年后进行活动能力(RMDQ)、疼痛程度(VAS)和直腿抬高试验(SLR angle)检查。RMDQ提高超过3分，VAS提高超过20分，就被认为临床有效。

结果：多方位快速牵引和纵向牵引均可使腰椎间盘突出症患者的RMDQ，VAS和SLR angle评分产生明显的改善(均有$P<0.05$)，两种方法的改善效果相似($P>0.05$)，但前者对活动能力(RMDQ)的改善更明显($P<0.05$)。临床疗效与患者的年龄、病程有关，但与突出大小、突出节段和类型的关系不大。所有的患者在治疗1年后症状都没有恶化。

结论：多方位快速牵引可更好的改善患者症状，且疗程短、见效快，是治疗腰椎间盘突出症的一种良好的保守疗法。

关键词 临床疗效；牵引；腰椎间盘突出症；疼痛；物理治疗

中图分类号：R681.5，R493 **文献标识码**：A **文章编号**：1001-1242(2011)-07-0638-06

DOI:10.3969/j.issn.1001-1242.2011.07.010

*基金项目：山东省自然科学基金(2008GG30002032)

1 Department of Physical Medicine and Rehabilitation, QiLu Hospital, Shandong University, Jinan, 250012, P.R.China;

2 Author for correspondence: Shou-Wei Yue, MD, Ph D(shouweiy@sdu.edu.cn)

作者简介：张杨，女，博士，主治医师； 收稿日期：2010-08-12

Lumbar disc herniation(LDH) is one of the major causes of low back pain[1].Treatment modalities for LDH generally include operative and non-operative management[2]. The pendulum has swung toward non-operative treatment, as long-term studies showed risk often increased in surgical intervention, while there were little differences in clinical effectiveness between operative and non-operative intervention[3]. The longitudinal traction(LT) is a common and non-invasive treatment for LDH[4], applies lower level traction force on lower lumbar vertebra for 30—60min and the treatment course is usually more than 10 times[5]. In 1990s, computer controlled multi-directional mechanical traction (MT) was developed in China. MT imitated the oblique pulling-rotating and interpolating-plucking manipulation of traditional Chinese medicine which has been successfully used for hundred years, to reset the instable vertebral body and treat low back pain[6]. Under the computer controlled, MT executes multi-directional traction simultaneously. The treatment duration only need a few seconds and its cost is 30%—50% of LT[7]. Up to date, over 50,000 patients with LDH have been treated by MT, and there are many successful case reports. However, the evidence for effectiveness of MT is weak due to high-quality studies are scarce. The purpose of this paper was to evaluate the effectiveness of MT on LDH in functional indices and pain severity, by comparing with LT.

1 Materials and Methods

1.1 Subjects

This study was conducted according to good clinical practice guidelines and approved by local ethics committee. Informed consent was obtained from each patient prior to the study. All the patients suffered from LDH were selected from outpatients of Department of Physical Medicine & Rehabilitation in Qilu Hospital from January, 2008 to December, 2008. A total 312 patients with LDH were screened, of which 120 patients were recruited into this trial, and informed as much detail as possible about the program before starting. Other 175 (56.1%) patients did not meet the inclusion criteria or meet the exclusion criteria and 17(5.4%) were eligible but chose not to participate the trail.

Inclusion criteria were: ① low back pain or sciatica due to LDH; ②LDH verified by CT scan; ③consistency in the pattern of pain complaint, neurological, and radiological findings. Exclusion criteria were: ① serious LDH (diameter of herniation is more than 8mm) or prolapsed herniation; ② low back pain due to neoplastic, inflammatory, infectious, tuberculosis, or metabolic causes; ③ spinal stenosis; ④ pregnancy, postpartum period, postoperative 3 months and menstrual period; ⑤ previous vertebral surgery; ⑥ the vertebral arch burst and severe osteoporosis; ⑦ being unable to tolerate traction due to cardiovascular disorder and diabetes mellitus. The baseline characteristics of patients were shown in Table Ⅰ. The follow-up assessments post 1 year were completed in December, 2009.

Table 1 Baseline characteristics of patients of both groups

	MT group(n=56)	LT group(n=57)
Years age($\bar{x}\pm s$)	39.09±8.25	37.96±7.58
Male(%,N)	67.9(38)	70.2(40)
Female(%,N)	32.1(18)	39.8(17)
Weeks duration($\bar{x}\pm s$)	47.2±38.5	36.3±33.3
Combined with other degenerative disc diseases(%,N)	19.6(11)	14.0(8)
Two levels or more levels herniation(%,N)	50.0(28)	42.1(24)
RMDQ(Mean, IQR)	16(3)	16(4)
VAS for pain($\bar{x}\pm s$)	60.4±10.9	59.8±13.5
SLR angle($\bar{x}\pm s$)	41.6±9.8	43.5±10.6

The baseline characteristics of the two groups were similar.

1.2 Procedures

The study was planned as a prospective, single-blind, randomized clinical trial. Each patient was randomly assigned to MT group or LT group. There were 60 patients in each group. Two physiotherapists were responsible for the initial screening of incoming referrals and onward referral of patients to the research therapist. The research therapist, who was blind to group allocation, measured the baseline and outcomes. Randomization was performed by an independent researcher who was not involved in the trial through a pre-determined randomization table. The schedule of group allocation numbered 1—120 was placed in a sealed opaque envelope taken out randomly. Patients and therapists were instructed not to reveal to the research therapist what treatment group they were allocated. Fig 1 showed the CONSORT flow diagram.

The MT group was treated with computer controlled multi-directional mechanical traction table, which was composed with a stable upper board and a mobile lower board (DFQ2600, Shandong Medical Instruments Institute,

P. R. China). The patient was instructed to take a prone position and keep relax. The upper torso and the lower torso were fixed on the upper and lower board respectively, with the involved segment on the gap between two boards (Fig2). During traction, the upper torso remained stationary and the lower torso was passively moved on the mobile caudal or "tail" section of the table. After the treating parameters such as traction distance, traction time, flexion range, and rotation angle were set, the pulling force was given automatically depended on the resistance force from muscles and ligaments of the patients′ waist to reach the target distance. The applied treatment was depended on the underlying symptoms, physical signs, auxiliary examination, sex, age and constitution, et al.

The treating parameters were often set as: ① traction distance (45—65 mm); ② flexion range (−10° —25°); ③ rotation angle (−25° —25°). The treating apparatus completed the longitudinal traction, flexion, and rotation automatically and simultaneously. The traction was lasted several seconds each time and repeated 2—4 times, with 60s interval between repetitions. The total duration of one MT treatment was several minutes. After MT treatment, the patient was asked to use waist belt for support and to rest in bed for 12d.

In LT group, the traction table(T-YZQ, Chang Zhou Qian Jing Rehabilitation Equipment Co. LTD, P. R. China) was used. Each patient was given a total of 12 sessions of longitudinal traction by a same physical therapist during the treatment period. Traction was administered for 5 min and followed with 5s of release, then repeated, 30min each session. Traction was started with the force equivalent to 25% of patients′ body weight and increased daily at set intervals until the 10th treatment; when traction force was set equivalent to 50% of the patients′ body weight, then the traction force was kept at this level to the end of the treatment course. After LT treatment, the patients were also asked to use waist belt for support and to rest in bed for 12d.

After MT or LT treatment, except analgesics, the patients did not receive any other physical therapy or manipulation therapy in the following 1 year.

1.3 Main outcome measures

Outcomes were measured at baseline and 4 weeks after MT or LT treatment. The average time between first follow-up and second follow-up examinations was 1 year. ① Disability was measured with Roland Morris Low Back

Figure 1 The CONSORT flow diagram

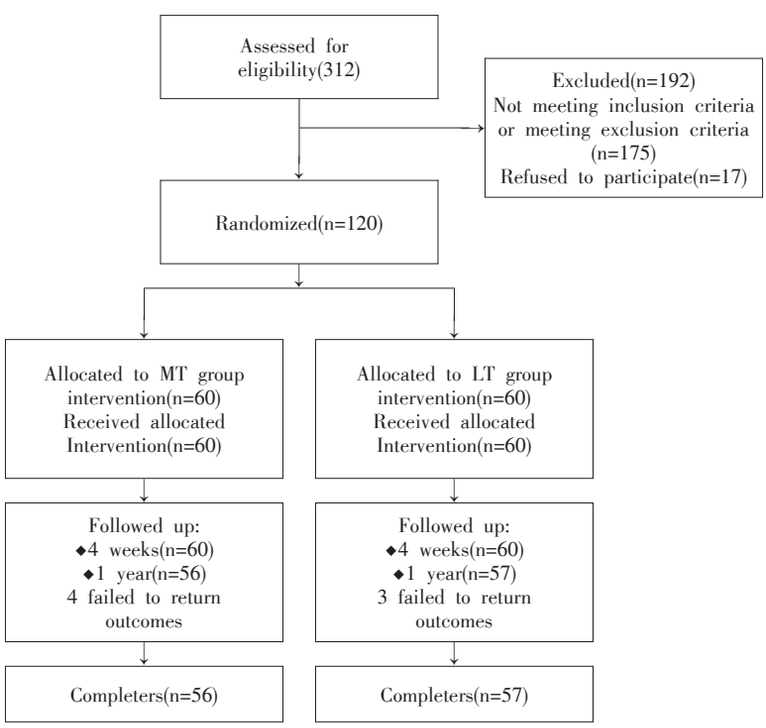
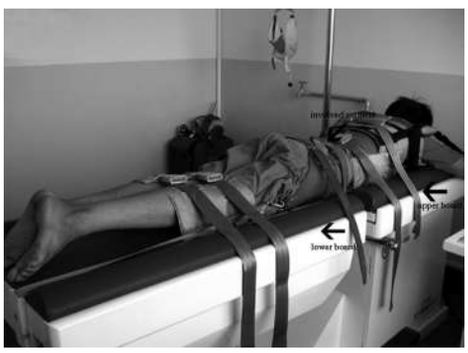


Figure 2 The DFQ2600 multidirectional traction table



The patient took a prone position and upper torso and lower torso were fixed on the upper and lower board respectively, which provided the traction force. The involved segment was on the gap between two boards.

Pain and Disability Questionnaire(RMDQ)[8]. After traction, if patient's RMNQ score improved more than three points, this effect could be estimated to be the threshold for clinically meaningful improvement[9]. ②The visual analogue scale (VAS) was used to evaluate the pain severity with unbearable pain severity set at 100 and no pain at all set at 0[10]. A twenty points difference was considered to be clinically effective[11]. ③The leg angle of straight leg raising (SLR) test was measured at hip joint with a goniometer ("SLR angle"). The range is between 0 and 90, with one point given for every degree in the SLR test.

1.4 Statistical analysis

A *t*-test, Mann-Whitney Rank Sum Test and Chi-square test were used to analyze the demographic and clinical characteristics of the patients when appropriate. Every protocol was performed for those completed treatment and followed up. Wilcoxon Signed Rank test was used to analyze the difference in RMDQ and *t*-test was used to analyze the difference in VAS and SLR angle between 3 time points and between two groups. Chi-square test was used to calculate the difference in the improvement ratios between two groups. Pearson correlation was performed to examine the correlation between the patient's age and functional improvement as well as the duration and functional improvement. $P<0.05$ was considered significant.

2 Result

There was no observable difference with respect to the initial demographic data and clinical characteristics before traction between two groups (Table1, all $P>0.05$). Wilcoxon Signed Rank Test and t-test revealed significant differences in all primary outcomes at 4 weeks post- and 1 year post-treatment compared with pre-treatment, regardless of treatment group (Table2,RMDQ: Wilcoxon Signed Rank Test, all $P<0.01$; VAS: t-test, all $P<0.01$; SLR angle: t-test, all $P<0.01$). No difference was observed in all primary outcomes between 4 weeks post- and 1 year post-treatment in both groups (all $P>0.01$). This indicated that both types of traction could improve patient's function, alleviate pain and provide long lasting improvements. Meanwhile, the MT group showed superior improvement in activities of daily living (RMDQ) 4 weeks post- and 1 year post-treatment compared with LT group (Wilcoxon Signed Rank Test, both $P<0.01$). No such difference was observed for either VAS score (*t*-test, both $P>0.05$) or SLR angle (*t*-test, both $P>0.05$). The improvement ratios in MT group were trended to be higher than those in LT group, but the differences were not significant (Table3, all $P>0.05$).

Patient's age and disease duration were identified as main factors affected the clinical outcomes. Significant negative correlations were found between RMQD score change and patient's age($P<0.05$) as well as disease duration ($P<0.05$). It appeared that a patient with better clinical outcomes had the statistically significant younger age and shorter disease duration (Table 4, all $P<0.05$).

3 Discussion

The main objective of this investigation was to evaluate and compare the clinical effectiveness of MT for the treatment of patients with LDH against LT. Results of observation indicated statistically significant gains to both groups. Though the differences in improvement ratios between two groups were not significant, patients in MT group were observed to experience significantly greater function improvement (via the RMDQ) after treatment. However perceived pain (according to VAS measurement) and SLR angle were not significantly different. In a natural history study by Baldwin[12], most patients would not be expected to improve over time, it confirmed that the clinical improvement was not influenced by the natural history of disease.

The lumbar traction is a commonly used treatment for low back pain in combination with other treatment methods[13].Cox et al. [14] reported on a series of 100

Table 2 The comparison of clinical outcomes of patients in MT and LT groups pre- and post-treatment

	MT group			LT group		
	Pre-treatment	4 weeks post-treatment	1 year post-treatment	Pre-treatment	4 weeks post-treatment	1 year post-treatment
RMDQ(Mean,IQR)	16(3)	8(4)①②	10(6)①③	14.7(3.1)	10.7(4.1)①	11.3(3.4)①
VAS for pain($\bar{x}\pm s$)	60.4±10.9	36.9±8.8①	37.8±10.1①	59.8±13.5	38.0±8.4①	39.0±9.6①
SLR angle($\bar{x}\pm s$)	41.6±9.8	60.2±12.6①	57.6±11.7①	43.5±10.6	60.2±12.4①	57.5±12.4①

Abbreviations:RMDQ,Roland-Morris Disability Questionnaire,VAS,visual analogue scale,SLR,straight leg raise,①P<0.05 compared to pre-treatment, ②P<0.05 MT group compared to LT group 4 weeks post- treatment,③P<0.05 MT group compared to LT group 1 year post-treatment

Table 3 The comparison of improvement ratio in MT and LT groups 4 weeks post-and 1 year post-treatment

Improvement ratio	MT group (%)		LT group (%)	
	4 weeks post-treatment	1 year post-treatment	4 weeks post-treatment	1 year post-treatment
RMDQ	80.5	71.4	68.4	66.7
VAS	57.4	57.4	57.9	50.9

Abbreviations: RMDQ, Roland-Morris Disability Questionnaire, VAS, visual analogue scale

patients with lower back pain (94 treated with distraction manipulation) and noted that 73% patients had good to excellent outcome. Ozturk et al.[5] compared the effectiveness of traction in combination with conventional physical therapy and found that lumbar traction was both effective in improving symptoms and clinical findings in patients with LDH. Consistent with those previous reports, our results showed that traction was an effective treatment for patients with LDH.

Table 4 The comparison of the age and duration of disease between patients with different clinical outcomes in MT group and LT group ($\bar{x}\pm s$)

	MT group				LT group			
	4 weeks post-treatment		1 year post-treatment		4 weeks post-treatment		1 year post-treatment	
	efficacy	inefficacy	efficacy	inefficacy	efficacy	inefficacy	efficacy	inefficacy
Years age	37.0±7.6①	46.3±4.9	37.8±8.2	42.4±7.6	34.8±6.8①	44.7±3.9	36.8±7.6	40.2±7.25
Weeks duration	36.3±31.2①	86.4±32.0	41.1±35.1	62.3±43.4	24.8±26.2①	61.4±33.8	28.3±31.0①	60.7±32.9

①P<0.05 efficacy compared to inefficacy.

MT is a new type of lumbar traction which imitates oblique pulling-rotating manipulation of traditional Chinese medicine. The maneuvers of longitudinal traction and anterior-flexion or posterior-extension and rotation can be executed simultaneously within a few seconds. The applied parameters were depended largely on the underlying symptoms, physical signs, auxiliary examination, sex, age and body constitution, et al. Rotation is used to correct the functional disorder of facet joint, such as joint subluxation and synovial interposing. To receive the MT treatment, patients had to go to the hospital only one time and the cost was 30%—50% of LT. In this present study, patients treated with MT had a better clinical effectiveness and shorter treatment time. MT treatment could overall place less financial and social burden on the health care system than those in LT treatment and other LDH treatments.

Our study showed that the clinical improvement was strongly correlated to the patient´s age and disease duration. Younger patients with shorter disease duration showed a better response to treatment. As one aging, the nucleus pulposus slowly degrades from a resilient and well-hydrated proteoglycan gel to a desiccated fibrocartilaginous substance that resembles the inner annulus more closely, and the disc begin to degenerate, radial tear may cause the nucleus pulposus protruding outside[15]. The longer disease duration often leads to more serious trauma. So the patient's age and disease duration could lower the effectiveness of treatment.

It is possible that the clinical improvements in MT treated patients were only temporary. However, a comparison of outcomes at 4 weeks and 1 year post-treatment indicated that the improvements were long-lasting, with minimal loss of RMDQ, VAS, and SLR angle in long-term follow-up.

The exact mechanism of traction is unclear. It is suggested that spinal elongation could lighten the lordosis and enlarge the intervertebral space, inhibit nociceptive impulses[16],improve mobility,decrease intradiscal pressure[17], reduce muscle spasm or spinal nerve root compression

(caused by osteophytes),release entrapped synovial folds or plica, rectify the pathological slope of facet joint, and disrupt articular or periarticular adhesions[18]. However, the proposed mechanism has not yet been supported with sufficient empirical information.

Besides LDH, MT is also effective for lumbar facet joint dysfunction, false spondylolisthesis, and earlier period ankylosing spondylitis. The contraindication includes serious LDH (diameter of herniation is more than 8mm), lumbar vertebrae neoplasm, inflammation and tuberculosis, cauda equina neoplasma, arcus vertebrae burst, osteoporosis, pregnancy, gross structural abnormalities, serious cardiovascular disease, and hemorrhagic tendency. Otherwise, we should weigh the merits and demerits before applying this treatment on patients with ossification of posterior longitudinal ligament and postoperative of nucleus pulposus removal.

Lumbar traction is an equipment aided treatment and it is possible to create complications, such as lumbar pain, abdominal distention and abdominal pain, herniations enlarging, and injury of cauda equine, et al. These complications can be avoided by carefully examining the CT image and strictly controlling the indications. In about 17 years of clinical practice, there was no major complication, such as herniations enlarging and injury of cauda equina.

It should be noted that there were many limitations in this study. Due to the small sample, we could not get a firm conclusion about the effects of different levels and different types of LDH. Meanwhile, we had not set no-treatment control group for ethical reasons. However, there was evidence in the literature to substantiate that most patients would not be expected to improve over time.

In conclusion, the multi-directional mechanical traction is more effective and superior to longitudinal traction in improving the symptoms and clinical findings of patients with LDH. The MT has unique merits such as short duration of treatment and lower cost making it a good treatment for LDH.

References

[1] Deyo RA, Loeser JD, Bigos SJ. Herniated lumbar intervertebral disk[J]. Ann Intern Med, 1990,112:598—603.

[2] Awad JN, Moskovich R. Lumbar disc herniations: surgical versus nonsurgical treatment[J]. Clin Orthop Relat Res,2006,443:183—97.

[3] McCulloch JA. Focus issue on lumbar disc herniation: macro- and microdiscectomy[J]. Spine, 1996,21:45S—56S.

[4] Postacchini F. Results of surgery compared with conservative management for lumbar disc herniations[J]. Spine, 1996, 21:1383—7.

[5] Ozturk B, Gunduz OH, Ozoran K, et al. Effect of continuous lumbar traction on the size of herniated disc material in lumbar disc herniation[J]. Rheumatol Int. 2006,26:622—6.

[6] Yu DF. Chinese traditional manipulation[M]. Beijing: People's Medicine Publishing House,1984.

[7] Liu CY, Zhang M, Wang YP, et al. The design and implementation of the spine-treating equipment with two coincided centers[J]. J Biomed Eng Res,2006,25:55—7.

[8] Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire[J]. Spine, 2000,25:3115—3124.

[9] Hurwitz EL, Morgenstern H, Harber P, et al. A randomized trial of medical care with and without physical therapy and chiropractic care with and without physical modalities for patients with low back pain: 6-month follow-up outcomes from the UCLA low back pain study[J]. Spine,2002,27:2193—2204.

[10] Deyo RA, Battie M, Beurskens AJ, et al. Outcome measures for low back pain research. A proposal for standardized use [J]. Spine, 1998,23:2003—2013.

[11] Farrar JT, Portenoy RK, Berlin JA, et al. Defining the clinically important difference in pain outcome measures[J]. Pain, 2000,88:287—294.

[12] Baldwin NG. Lumbar disc disease: the natural history[J]. Neurosurg Focus,2002,13:E2.

[13] Harte AA, Gracey JH, Baxter GD. Current use of lumbar traction in the management of low back pain: results of a survey of physiotherapists in the United Kingdom[J]. Arch Phys Med Rehabil, 2005,86:1164—1169.

[14] Cox JM, Fromelt KA, Shreiner S. Chiropractic statistical survey of 100 consecutive low back pain patients[J]. J Manipulative Physiol Ther,1983,6:117—128.

[15] Buckwalter JA. Aging and degeneration of the human intervertebral disc[J]. Spine,1995,20:1307—1314.

[16] Clarke J, van Tulder M, Blomberg S, et al Traction for low back pain with or without sciatica: an updated systematic review within the framework of the Cochrane collaboration[J]. Spine,2006,31:1591—1599.

[17] Ramos G, Martin W. Effects of vertebral axial decompression on intradiscal pressure[J]. J Neurosurg, 1994, 81:350—353.

[18] Evans DW. Mechanisms and effects of spinal high-velocity, low-amplitude thrust manipulation: previous theories[J]. J Manipulative Physiol Ther,2002,25:251—262.