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Does Newly Developed Lordotic Curve Controlled Traction Treatment Change Long Term Health Status in Patients with Herniated Lumbar Disc Disease : Randomized Controlled Trial

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A B S T R A C T

The lumbar lordotic-curve controlled traction device (LCCT) has been newly developed. But there has been few studies to evaluate the long term comprehensive health status change after traction treatment. The purpose of our study was to compare the long term health status changes between LCCT and standard traction (ST) device with randomized controlled trial design. Total 40 patients with or mild non-radicular low back pain (LBP) were included in this study. With random order, all the participants were classified either into LCCT group or ST group. The comprehensive health status changes of the patients were recorded using visual analog scale and SF-36 initially and after 3 months traction treatment. In results, The LCCT group showed a significant reduction in pain intensity($p<.05$), and greater improvement in physical functioning, physical role functioning, bodily pain, emotional role functioning of SF-36 than ST group($p<.05$). No significant adverse effect was reported in both groups. Due to its ideal advantages of maintaining the natural lordotic curve during spinal traction, the newly developed LCCT showed a significant advantages in improving comprehensive health status especially scores. The clinical benefits of LCCT appears to last long time thus it could be suggested in clinical settings.

K E Y W O R D S : LCCT, Lordotic Curve, Lumbar Disc, Pain, Health

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I. Introduction

Herniated lumbar disc intervertebral disease (HIVD) has been known to one of the major causes of back pain[1]. In patients with HIVD, people suffer neurological complications in addition to pain and discomforts in long periods of time. Pain and discomfort often causes functional deteriorations and needs a lot of medical expenses[1]. Thus it appears to be significant important to treat back pain with various treatment options including conservative and surgical methods[2-6].

One of the conventionally used non-invasive treatment options is traction method. Spinal traction provides a means of spinal decompression and was designed to straighten the spine to improve spinal alignment. Of the many beneficial effects of spinal traction, its main effects are to provide pain relief, to achieve spinal alignment, and to relieve pressure on nerves in HIVD patients[7].

Despite the theoretically favorable effects of spinal traction devices, clinical reliance on traction therapy for the treatment of lumbar disk disease is low. Improper pressure loading on disc structures during traction is a possible explanation for this lack of clinical efficacy. However, mixed results has been reported despite its theoretical advantages[8-12]. Due to the limitations of the high -quality randomized controlled studies, small sample size, different treatment technique and protocols, no clear benefits of the traction treatment has been reported[8, 10].

Some authors suggested possible explanations of the poor results. One of the explanations of the poor outcome is the ‘deterioration of the natural lordotic curve’ during traction treatment[13]. In the supine position, the lordotic curve decreases due to vertical pressure on lumbar curve, which is severe in patients with low back pain[14]. As a result, when traction force is applied to the spine in the supine position, its main effect becomes to straighten the natural lordotic curve due to body gravity and traction direction. And thus, rather than decompressing intervertebral disks, spinal traction decreases the lordotic curve and thus gives unnecessary traction force to the posterior column structures[15]. Posterior spinal structures, such as, facet joints and posterior longitudinal and interspinous ligaments, are elongated more than anterior spinal structures[15]. It happens when traction pressure is applied to the spine in the supine position using a standard traction device(ST), the lordotic curve decreases at the expense of equal distraction of the whole spinal structure, and resultantly, pain develops.

Thus maintaining the natural lordotic curve during traction treatment appears to be one of the crucial factor not to cause any discomfort or pain. Thus, we considered if we could apply traction force to vertebrae while maintaining the lordotic curve, the force would be distributed equally to the anterior and posterior parts of the spinal structure. Subsequent development resulted in a lumbar lordotic curve controlled traction device (LCCT) targeting the L4/5 intervertebral disk space.

Up to date, a brief improvement of pain after traction treatment has been reported in many studies, there has been a few studies to evaluate the comprehensive health status change after traction treatment[16]. In general, short pain improvement doesn’t always correlate with a long term comprehensive health status change after the traction treatment, as comprehensive health status including vitality, physical functioning, bodily pain, general health, physical role functioning, emotional role functioning, social role functioning, and mental health can only occur after significant structural effect. More than that, although there was a significant improvement of pain, it also needs some time, at least several weeks, to influence one’s emotional, functional, and social changes which had been habitual to them. Thus comprehensive evaluation throughout at least some period of time should be considered to

measure the efficacy otherwise it may yield a false negative results after traction treatment. However, there were few previous studies to compare the comprehensive health improvement change throughout long period of time after traction treatment.

Thus the purpose of our study was to evaluate the comprehensive health status change of the LCCT after 3 months and compare with ST in patients with HIVD with randomized controlled trial study design.

II. Methods

2.1 Subjects

This study was designed as randomized controlled trial comparing between LCCT and ST. The subjects of this study were 40 patients (male 19 and 21 female) between 20 and 65 years, who visited our hospital between Jun 1, 2016, and Feb 28, 2017, and were diagnosed as lumbar herniated intervertebral disc between the L4-5 and L5-S1 from MRI. In this study, Excluded patients with acute inflammation, unstable cervical vertebral, joint hypermobility, inhibited flexion or extension of the lumbar vertebrae, having released disc fragments, patients whose symptom could be exacerbated by traction therapy or had pain in waist due to traction therapy, or patients with diseases that could affect the spinal cord including spinal cord infections, spinal cord compression, spine infection, and meningitis, patients with osteoporosis, patients with rheumatoid arthritis, patients with claustrophobia, patients with heart or respiratory failure, and regnant patients based on previous studies[15]. All study subject received sufficient explanations regarding the objectives and methods of the study before participating in the study. This study has been registered in the Korea (IRB 04-2016-029).

2.2 Procedures

All subjects were randomly assigned either into LCCT or ST group. Patients were randomly assigned into two groups (LCCT or ST) by a research physician with the help of a computer generated table of random numbers. All the subjects did not know what group they belonged to. The evaluations were carried out by a physician who was blinded to the treatment.

The Lordotic Curve Controlled Traction Device (KINETRAC KNX-7000, Hanmed Co., Republic of Korea) was used to maintain the natural lordotic curve by supporting the lumbar curve at the L4/5 intervertebral disk space. Initially a magnetic marker was attached on the L4/5 intervertebral disk space by physical palpation, and an automated tracking system [Figure1]. Lied in supine position, the chest and pelvic were belted to provided support. The operating range of the device does not exceed the range of human body's motion. Also, the maximum traction power of the device does not exceed 100 pound or 50% patients weight in order to prevent damage the muscle or tendon of the patients.

ST group was applied to the subjects without supporting lumbar lordotic curve. Following the same protocol of LCCT, the subjects were lied in supine position and ST traction was applied. All the subjects received traction 5 days per week for 3 months. The duration of the traction was 15 minutes and total 60 times of tractions were applied in both groups.

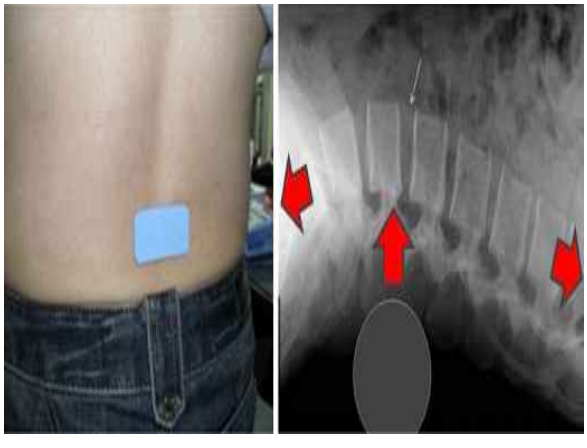

Fig1. A magnetic marker was attatched on the L4/5 intervertebral disk space and automated tracking system elevates the marking site.

2.3 Outcome measures

(1) Visual Analog Scale

Pain in the trunk and lower extremities that was exacerbated during activities of daily living were measured initially, at the end of the treatment session and 3 months after initial assessment using a 10 mm Visual Analog Scale(VAS)[2].

(2) SF-36

We evaluated the comprehensive health status of the patients using SF-36 scale[16] before and 3 months after treatment. The eight sections consists of vitality(VT), physical functioning(PF), bodily pain(BP), general health(GH), physical role functioning(RP), emotional role functioning(RE), social role functioning(SF), mental health(MH) and the score of each categories are total 100.

2.4 Statistics

Sample size analysis showed for a two-sided level of significance of 0.05 and an interclass correlation of 0.8 at least 40 participants were required, and thus, 40 patients were enrolled to cope with potential losses. The data were analyzed using the paired t-test and independent t-test. The significance level was set at $p<0.05$. The SPSS software (ver. 22.0) was used.

III. Results

3.1 Comparison of general characteristics of subjects, pain and SF-36 between groups before intervention

The LCCT group included 11 females and 10 males (48.75±13.32). The ST group included 10 females and 9 males (41.00± 16.00). No special variables related to the general characteristics of the subject were found between the groups, thus indicating homogeneity ($p>.05$)[Table 1]. During 3 months of study period (total 60 times of traction treatments), there was no loss of clinical follow up. Before intervention, there were no significant differences between groups in VAS and SF-36($p>.05$)[Table 2].

Table 1. General characteristics of participants

	LCCT (n=21)	ST (n=19)
Age (years)	48.75±13.32	41.00±16.00
Height (cm)	163.60±7.47	167.63±9.21
Weight (kg)	62.35±11.22	64.90±12.00
BMI	23.23±3.40	22.96±2.97

Values are expressed as mean±SD. LCCT: Lumbar lordotic curve controlled traction device; ST: Standard traction device; BMI: Body mass index

Table 2. Comparison of pain and SF-36 between groups before intervention

		LCCT (n=21)	ST (n=19)	p
VAS		6.30±1.59	5.90±1.61	.436
SF-36	PF	65.16±19.09	66.39±19.39	.613
	RP	60.21±2058	61.44±28.13	.877
	BP	46.42±25.30	51.05±22.38	.559
	GH	47.89±10.58	46.94±16.46	.835
	VT	38.63±14.86	42.50±17.74	.478
	SF	69.89±21.01	57.55±25.67	.760
	RE	63.58±24.97	76.50±26.80	.143
	MH	60.79±19.95	68.88±20.33	.230

Values are expressed as mean±SD. LCCT: Lumbar lordotic curve controlled traction device; ST: Standard traction device; VAS: Visual analog scale; PF: Physical functioning; RP: Physical role functioning; BP: Bodily pain; GH: General health; VT: Vitality; SF: Social role functioning; RE: Emotional role functioning; MH: Mental health

3.2 Changes of pain and SF-36 within groups before and after intervention

The LCCT group showed a significant reduction in VAS and incresed in all subscale of SF-36 before and

Table 3. Changes of pain and SF-36 within groups before and after intervention

		LCCT (n=21)			ST (n=19)		
		Before	After	*p*	Before	After	*p*
VAS		6.30±1.59	3.15±0.81	<.001***	5.90±1.61	4.55±1.60	<.001***
SF-36	PF	65.16±19.09	78.16±13.97	.001**	66.39±19.39	67.50±17.59	.780
	RP	60.21±2058	86.68±17.50	<.001***	61.44±28.13	66.11±27.21	.408
	BP	46.42±25.30	75.11±17.22	<.001***	51.05±22.38	61.16±25.80	.017*
	GH	47.89±10.58	59.74±12.96	.006**	46.94±16.46	53.61±15.12	.090
	VT	38.63±14.86	58.05±17.75	.002**	42.50±17.74	51.83±19.02	.048*
	SF	69.89±21.01	86.42±15.89	.001**	57.55±25.67	77.16±21.45	.024*
	RE	63.58±24.97	90.84±19.58	.001**	76.50±26.80	77.27±17.34	.893
	MH	60.79±19.95	77.37±14.18	.003**	68.88±20.33	73.05±17.56	.344

Values are expressed as mean±SD. LCCT: Lumbar lordotic curve controlled traction device; ST: Standard traction device; VAS: Visual analog scale; PF: Physical functioning; RP: Physical role functioning; BP: Bodily pain; GH: General health; VT: Vitality; SF: Social role functioning; RE: Emotional role functioning; MH: Mental health

*p<.05, **p<.01, ***p<.001, significant differences within groups

Table 4. Comparisons of change values of pain and SF-36 between two groups after intervention

		LCCT (n=21)	ST (n=19)	*p*
		Change values	Change values	
VAS		-3.15±1.49	-1.35±0.99	<.001***
SF-36	PF	15.00±15.63	1.11±16.59	.013*
	RP	26.47±24.91	4.66±23.33	.010*
	BP	28.68±22.79	10.11±16.18	.007**
	GH	11.84±16.43	6.67±15.72	.335
	VT	19.42±23.11	9.33±18.62	.154
	SF	16.52±18.09	9.61±16.43	.233
	RE	27.26±31.73	0.78±24.08	.007**
	MH	16.58±21.41	4.17±18.17	.066

Values are expressed as mean±SD. LCCT: Lumbar lordotic curve controlled traction device; ST: Standard traction device; VAS: Visual analog scale; PF: Physical functioning; RP: Physical role functioning; BP: Bodily pain; GH: General health; VT: Vitality; SF: Social role functioning; RE: Emotional role functioning; MH: Mental health

*p<.05, **p<.01, ***p<.001, significant differences within groups

after intervention(p<.05). The ST group showed a significant reduction in VAS and incresed in BP, VT, SF of SF-36 before and after intervention(p<.05). PF, RP, GH, RE, MH of SF-36 were not significant change(p>.05)[Table 3].

3.3 Comparisons of change values of pain and SF-36 between two groups after intervention

The LCCT group showed a significant reduction in pain intensity(VAS)(p<.05), and greater improvement in PF, RP, BP, and RE of SF-36 than ST group(p<.05). There were no significant differences between groups in GH, VT, SF, and MH(p>.05)[Table 4].

Ⅳ. Discussion

Despite its theoretical favorable effects on spinal traction device, the clinical reliance on standard traction method for the treatment of lumbar disc

disease has been low in clinical setting[17-20]. As we mentioned earlier, it might be due to poor guideline about traction method and individual differences of the patients. In addition, we suggested the possible explanation that standard traction device theoretically decrease the lordotic curve in supine position. Thus, the newly invented LCCT could possibly decompress the intervertebral disc pressure equally while maintaining the natural lordotic curve during traction even in supine position.

In our study we could acquire the favorable results in group with LCCT compared to ST. As we mentioned earlier, pain improvement can occur right after the treatment, however, it does not necessarily means the comprehensive health status change after treatment. In this study, we exclusively focused on the comprehensive long term health status change using SF 36 form. In this study, both groups showed a significant decreases in pain scores after 3 months treatment. However, the amount of pain reduction in LCCT was higher than ST and the patients showed a significant improvement compare to the ST at 3 .

In addition to simple pain reduction after traction treatment, LCCT showed a significant comprehensive health status improvement than ST at 3 month. Especially, LCCT was higher than those of ST at 3 months. The pain of the patients can change according to individual, environmental and chronologic factors thus it might not directly reflect the permanent comprehensive health status. In this sense, the significant change of SF-36 in LCCT appears to be a significant results which stands for the long term and permanent clinical advantages of LCCT over ST.

Theoretically, LCCT has an advantage over ST in maintaining the natural lordotic curve during traction. As we already mentioned, adjusting the natural lordotic curve during supine position resulted equal distribution of the traction force anteriorly and posteriorly. We also acquired the same results from the LCCT not to cause any discomfort or pain.

However there are several limitations in our study. First, although we recruited enough sample size, more subjects with difference sex and age could be recruited to generalize our results. As the disease status vary individually, the results have to be carefully re-evaluated before applying in clinical settings. Second, although we experimented HIVD patients according to our guidelines, our methods could be different with other clinical settings. In addition, the clinical results could be different according to therapists or individual specific conditions. Thus special consideration should be given before generalization of our results.

In spite of several limitations, our study could be meaningful in terms of complementing theoretical weakness of traction device with randomized controlled clinical trial study. Thus, maintaining its original lumbar lordotic curve should be considered while applying traction device in clinical settings. As the lordotic curve could be decreased or deteriorated during standard type of traction, the poor results of the previous studies should be re-evaluated and thus could make favorable outcomes. In addition to its geometrical modification, we evaluated the clinical effect of LCCT with comprehensive health status measurement tool using SF-36 with long time interval with randomized controlled trial. Based on our results, further study will be needed to re-establish the traction guideline such as intensity, interval and frequency of the treatment to make a best results.

Ⅴ. Conclusion

Due to its ideal advantages of maintaining the natural lordotic curve during spinal traction, the newly developed LCCT showed a significant advantages in improving comprehensive health status especially scores. The clinical benefits of LCCT appears to last long time thus it could be suggested in clinical settings.

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요추 전만각 증가식 견인 치료가 요추 추간판 탈출증 환자의 장기간 건강 상태를 변화시킬 수 있는가 : 무작위 대조 실험

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요 약

요추 전만각 증가식 견인장치(lumbar lordotic-curve controlled traction device, LCCT)가 새롭게 개발되었으나 견인 치료 후 장기간 건강 상태의 변화를 평가한 연구는 미흡하였다. 본 연구의 목적은 LCCT와 기존의 견인장치(Standard traction, ST) 사이의 장기간 건강의 변화를 무작위 대조 시험 설계를 통해 비교하고자 하였다. 본 연구에 40 명의 경한 요통이 있는 환자가 참여하였다. 모든 참가자는 LCCT 그룹 또는 ST 그룹으로 무작위 할당되었다. 환자의 전반적인 건강상태는 시각상사척도와 SF-36을 사용하여 치료 전과 치료 후 3개월의 변화를 평가하였다. 그 결과, LCCT 그룹은 ST 그룹보다 통증 강도가 현저히 감소하고 신체 기능, 신체 통증, 정서적 역할 등이 크게 개선되었다. 두 그룹 모두에서 유의한 부작용은 보고되지 않았다. 척추 견인 동안 자연적인 성인의 곡선을 유지하는 이상적인 이점 때문에, 새롭게 개발된 LCCT는 종합적인 건강 상태, 특히 통증 점수를 개선하는데 있어 상당한 이점을 보였다. LCCT의 임상적 이점은 장기간 지속될 것으로 보여 임상 환경에서 제안될 수 있다.

핵심어 : 요추 전만각 증가식견인, 요추전만, 요추간판, 통증, 건강

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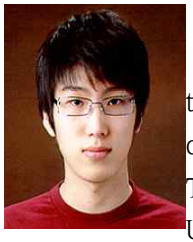

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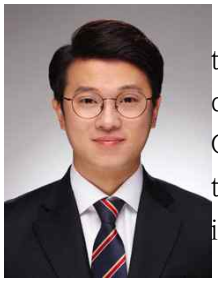

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