SOUTH BAYLO UNIVERSITY

Effect of Acupuncture Treatment on Chronic Low Back Pain Caused by Motor

Vehicle Accident: Case Series

by

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ABSTRACT

The purpose of this case series study was to establish systematic and effective treatment method of acupuncture treatment for the patients with chronic low back pain caused by motor vehicle accident (MVA). 7 participants were treated 8 session of acupuncture treatment on BL23, BL24, BL25, BL40, BL60, GV3, GV4, Ex21, LU9+, SP3+ and LI11-. The outcomes were measured by Visual Analogue Scale (VAS) every before and after treatment and Oswestry Disability Index (ODI) before, after 4th and 8th treatment respectively. The data were collected and processed to calculate, treatment rate, effect size and regression analysis. VAS was improved from 7.53 ± 1.02 to 1.19 ± 2.22 (*p*=0.001) before and after 8th treatment, treatment rate was improved to $83.46\pm31.35\%$, effect size was calculated as 3.71 and evaluated as huge, the appropriated number of

treatment was calculated as 5 to 9 times by regression analysis. And overall ODI% was decreased significantly from $43.9\pm8.0\%$ to $21.3\pm14.8\%$ (*p*=0.011). It was concluded that 5 to 9 times of acupuncture treatment including SP3+, LU9+ and LI11- is effective significantly to the chronic law back pain caused by motor vehicle accident. Also based on this result I propose a larger scale and higher quality clinical trial.

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I. INTRODUCTION

In the United States, more than 6 million Motor Vehicle Accidents (MVA) occur and more than 2.44 million MVA patients arise per year. This has cost the US economy over 242 billion dollars.^{1,2)} In addition, the issue of social and economic effects caused by traffic accident, has been getting attention as the most important topic. World Health Organization predicts that by 2020, fatalities and casualties occurred in countries all over the world from this will have made this the 3rd highest issue.^{3,4)}

Pain derived from MVA most commonly occur at the neck (28%) and lower back (26%) which if not cured within 12 weeks, progresses to become chronic. $^{5,6,7)}$ 30 to 42% of patients experience low back pain (LBP) for 6 months; 40.5% after 2 years; and 20% of patients still experience pain after 7 years.^{8,9,10)} Pain caused from MVA including LBP, mostly progress to chronicization as musculoskeletal disease, and its prognosis and rehabilitation continue to be slow. Therefore, this remains to be studied in a personal and social level.^{11,12,13} Treatment options used for Chronic LBP induced from after effects of MVA are as follows^{14,15}: surgery, medication, injection therapy, physical therapy, behavioral therapy, manual therapy, manipulative therapy, wearing supportive gears, electrostimulation and acupuncture.^{15,16,17)} The efficacy of conservative treatments of LBP in a randomized control group are being studied more actively and systematically in the beginning of 21st century.^{18,19,20,21,22,23)} The acupuncture, an oriental medicine, is becoming widely known for its efficacy and cost effectiveness, and it is raising interest in Contemporary and Alternative medicine (CAM).^{24,25)} The main reason patients seeking CAM is due to LBP and shoulder pain. Among these patients 41.2% choose CAM for their treatment choice.^{19,26,27,28,29)} Studies showed that Acupuncture (64.6%) had the highest efficacy compared to Chiropractic therapy (62%) and Massage therapy (54.7%).²⁶⁾

Acupuncture is being widely used for chronic LBP but one of the main cause,^{16,30,31,32,33,34,35)} MVA caused LBP, is not yet understood and the study for an effective treatment is incomplete. LBP from a common cause is located between the lower costal margin and upper hip with pain from muscle tension, spasm or shortening regardless of the existence or nonexistence of radiating pain to the leg. Whereas LBP caused by MVA is pain caused by sudden impact and physical reaction which is a condition that elicits soft tissue damage and starts from the paravertebral and progresses to damage the spinal discs, intervertebral disks, sacroiliac joints with muscles, ligaments, and articular capsule.^{8,15)} Treating LBP Injury caused from external trauma with acupuncture has been studied already in the eastern medicine, yet its systematic study is insufficient.^{36,37)} In 1993, Korea has started a study involving 260 MVA cases that were treated for external injury to the damage of Qi flow and its absence leading to blood stagnation. Acupuncture, herbal decoction, moxibustion, and cupping were used but these were not for chronic LBP but limited for LBP treatments of 12 weeks or less. In addition, treatment protocol also included and combined prescription drugs and physical therapy.^{36,38,39,40,41)}

This Study involves MVA induced LBP in which the clinical research has been constructed to find the effect of series of acupuncture treatments on patients whose pain didn't resolve after the initial treatment but remained as chronic LBP. Insurance covered treatments may resolve pain only temporarily but the pain lingers afterwards and progresses into a chronic state and in such case becomes a medical blind spot only to stay as a personal and societal burden. Thus this study was designed to establish an Oriental medicine treatment method for MVA caused LBP. The diagnosis is Qi and Blood stagnation causing pain and the treatment method is to move Qi in the back area and remove blood stagnation from the whole body. And to investigate the efficacy the study was carried out in a series of case studies. Based on those results, a randomized clinical trial was suggested.

II. OBJECTIVES

The objective of the research is to look into the efficacy of acupuncture treatment lowering patient's pain level and lower back functions when treating MVA induced chronic LBP and the details are as follows.

Objective 1. To verify the efficacy of acupuncture treatment lowering pain level (VAS) on MVA derived chronic LBP.

Objective 2. To calculate the cumulative cure rate, size of effect and number of acupuncture treatments on MVA derived chronic LBP patients.

Objective 3. To verify the improvement of LBP and its functions by using acupuncture treatment through studying MVA derived chronic LBP patients.

Objective 4. To establish effective acupuncture treatment method for patients with MVA derived chronic LBP.

Objective 5. To provide the need for a research that is higher in quality and much larger scale regarding patients with LBP derived from MVA.

III. LITERATUE REVIEW

3.1. Characteristic of MVA

The sudden decrease in speed and impact during a MVA increase weight on the passenger's posterior and inferior spine through the inertia of the vehicle and rebound of the body.⁸⁾ The resulting pain condition of MVA is reflected mainly in the cervical, thoracic and lumbar of the spine.⁵⁾ At the early stage after MVA, the symptom that's most frequently observed is pain associated with what's called whiplash. This symptom has usually been the focus.^{42,43)} However, whiplash has further been studied to reveal that Whiplash-Associated Disorder (WAD), which not only affects the cervical part but progressed to also show cognitive and physical symptoms. Recently, it has been confirmed that its pain is widespread.^{5,44,45)} Investigation showed that WAD associated and induced LBP accounts for 55% and independently arising LBP account for 26%.^{5,46)} Moreover, such pain has been classified as chronic LBP if persisting longer than 12 weeks without improvement. It has been reported that 30-42% of patients experience LBP for 6 months, 40.5% still experience LBP after 2 years, and 20% still experience

LBP due to ordinary causes is pain arising between the infracostal region and pelvic region from muscle tension, spasm, contraction, etc. And it's a symptom that appears regardless of presence or absence of radiating pain. But MVA caused LBP causes soft tissue damage due to pain from sudden impact and body rebound. This further affects the disks at the axis of the spine, facet joints, sacroiliac joints and muscles, ligaments, articular capsule, etc.^{8,47)} It is certain that such MVA impact caused Whiplash Associated

Disorder (WAD) regarding progressing LBP may appear differently but the mechanism that causes and prolongs the pain still remain unknown.⁴⁷⁾

3.2 Treatment principle of MVA

The treatment guideline regarding MVA caused pain is being guided in combination with WAD and most of the treatments are initial treatments meaning they occur within 12 weeks after the initial pain occurs.^{47,48)} This method of treatment guideline recommends, manual therapy including stretching, joint mobilization, manipulation therapy, exercise therapy, patients education, and complementary and alternative program. In the case where the patient doesn't recover within 3 months, they are recommended to refer to a whiplash specialist, psychologist for further evaluation or self-manage at home. However, they do not receive a recommendation for a systematic solution.^{47,48)} Teasell et al (2010) differentiates treatment methods based on acute (within 2 weeks), non-acute (2-12 weeks), and chronic (more than 3 months). The treatment methods are as follows:^{14,49,50,51,52)}

Mobilization programs

Using a treatment method to stabilize the cervical is not as effective as active treatment and less than natural treatment. Active treatment has been proven to effectively lessen pain and increase ROM but it hasn't been proven to be more effective than natural treatment.

Manual joint manipulation including interdisciplinary interventions

Research shows that manual therapy is effective for early onset and short term (1week - 1month) of pain treatment. But due to conflicting data, it was announced that it is difficult to draw conclusion and needs further research. Physical therapy and behavior recognition have been reported to be effective for pain and disability index but additional studies were done after 3 months have shown no significant difference. While manual therapy in conjunction with psychotherapy have been reported to be effective, other research have found it not important.

Exercise programs

Exercise programs don't have a definitive effect on chronic pain but have been declared to be effective for acute pain. However, treatment for non-acute pain is non-effective and notably active physical therapy type has been also declared to be potentially a hindrance for recovery. There is also a report where a supervised physical therapy treatment has led to a higher efficiency compared to a non-supervised program. Studies revealed that specific physical therapy methods have been effective in relieving pain regarding chronic pain.

Pharmacological interventions

Methylprednisolone, a subsidiary of steroids that treat inflammation, has been shown to be effective for acute pain but this needs an additional larger sample study. Melatonin supplements have shown efficacy in prolonging melatonin release time but did not show to alleviate pain in chronic pain treatments.

Educational interventions

Despite the fact that educational programs can be utilized for acute pain they have not shown any definitive effect. Nevertheless, there is a statistic that media with verbal education is more effective than handing out pamphlets.

Alternative treatments

Pulsed Electromagnetic Field Therapy (PEMT) has been rumored to be effective in increasing ROM, yet there is no concrete evidence. A study showed that laser acupuncture treatment was less effective than a placebo treatment. There is confirmed limited evidence that Myofeedback treatment is effective for chronic pain. One of the psychotherapies, the combination of Gestalt therapy, Rosen bodywork and craniosacral therapy, has not been able to show much of effectiveness for chronic pain.

Injection-based interventions

Studies on botulinum toxin injections have not been able to show that it was more effective than a placebo treatment. Studies showed that Sterile water injections, Corticosteroid intra-articular and selective nerve root injections don't have much effect on chronic pain, whereas there is a contradictory evidence for BTXA injections.

Surgical interventions

Despite the efficacy of Radiofrequency neurotomy for chronic pain, further study needs to be carried out to see if patients can get meaningful effect.

As examined above, chronic pain induced by auto accident does not have a treatment method established specifically for LBP including overall WAD treatment. Furthermore, conflicting conclusions are drawn without systematically establishing a treatment method for MVA as well as emerging of opinions that randomized control studies are insufficient regarding the treatment method. Therefore, a systematic clinical research needs to be carried out not on just LBP but also on WAD in a big enough scale that can be used in a Meta Analysis.

3.3 Oriental Medicine treatment method

On the other hand, oriental medicine has been performing treatments having placed MVA induced pain as external injury due to external impact.⁵³⁾ When Blood and Qi of a meridian are injured and become stagnated, it causes Qi & Blood stagnation and results in pain.⁵³⁾ The objective of the treatment was to circulate blood and Qi to get rid of bad blood (stagnated blood, evil blood, or virulent blood) that was produced when outside trauma caused the limbs and five Zang organs to move.^{37,54)}

When it comes to LBP, many diseases can become the cause for LBP. According to Chinese Acupuncture and Moxibustion (CAM) book, the causes are form external cold damp, internal injury of Kidney Qi, or sprain from external injury. According to Danxi's mastery of medicine, it is caused by damp heat, kidney deficiency, blood stagnation, sprain, or phlegm accumulation.^{37,55)} In case of chronic LBP, the back is the house of the lords according to Huangdi Neijing and the main symptoms are seen as Kidney Deficiency. It was determined that MVA induced LBP was caused when meridian's Qi and blood are damaged it leads to Qi and blood stagnation which in turn leads to LBP.

This illness was revealed to be sprain from external injury.^{37,54,56)}

Treatment principle for this is to first move qi to soothes the sinews and invigorate the collaterals by needling the meridian points of the Du channel and foot tai yang channel that are located at the back and spine. It also tonifies Kidney Yang and Kidney Yin deficiency that are due to chronic illnesses. The movement of blood is derived from movement of Qi. Therefore, by harmonizing both qi and blood, the stagnant blood stagnation can be removed.^{53,57)} The combination of the acupuncture point selection is helping kidney qi by needling ShenShu (BL23), and helping tonify Kidney Yang and Kidney Essence by needling MengMun (GV4) and YaoYan (EX21). Needling YaoYangGuan, DaChangYu (BL25), will unblock the channels and stop pain locally and WeiZhong (BL40) will treat low back pain and as a distal acupuncture point.⁵³⁾

The cause for blood stagnation are Qi deficiency, Qi stagnation, blood clot, external trauma with other causes causing blood's movement to be unnatural, the flow of Qi to stagnate, or because internal hemorrhage was not dissipated on time. When this blood stagnation stays in the muscles and veins and prevents Qi and blood to clear, LBP will result in a violent manner. Treatment for blood stagnation is by clearing and moistening the lung Qi to unblock the qi stagnation. As called 'Qi is the commander of the blood', circulation of blood is derived from the movement of Qi and so unblocking Lung Qi with Zong Qi's movement becomes the precondition for blood circulation. The purpose of selecting the acupuncture combination of tonifying TaiYuan (Lu9+) and TaiBai (SP3+) unblocks Lung Qi and restores the movement of Qi that was once absent and sedating QuChi (L111-) will provide moisture to soften the hard and smooth the Qi movement.^{53,57,58,59})

IV. MATERIALS AND METHODS

4.1. Materials

4.1.1 Thin sterile needle

The acupuncture needles used in this research were sterile, disposable and made of stainless steel and 0.20mm x 30mm (diameter x length). Used needled were discarded in biohazard sharps container as guidelined by the CNT regulations.

4.2. Methods

4.2.1. Research Plan

This research h plan involved patients who had a history of auto accidents and who continued experiencing LBP after receiving corresponding treatments. These patients were then given acupuncture treatments to see the effect on how it would alleviate their pain. Patients who met the selection criteria were given 8 treatments and the results were analyzed by comparing the before and after of VAS (Visual Analogue Scale) and ODI (Oswestry Disability Index) (Figure 1).

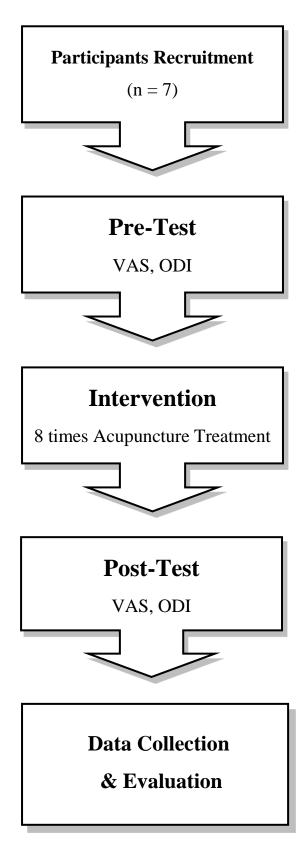


Figure 1. Schematic Diagram of Study Design

4.2.2. Subject of Study

The subject of study involved patients who voluntarily participated in this study from March, 2017 to August, 2017 at the Pro Care Pain Clinic. The selection took place after the Informed Consent Form and the research proposal had been approved by South Baylo University's IRB (Institutional Review Boad).

4.2.2.1. Patient selection and exclusion criteria

Patient selection criteria were as follows: patients who had a history of receiving treatments for MVA and still continued to experience LBP after initial treatments, experience pain beyond 3 months with VAS score of 5 or above, those who understood the case study and agreed and signed the participation form. Patient exclusion criteria were as follows: Patients whose LBP was acute and less than 3 months, no history of MVA, had a history of surgery for the LBP, and currently undergoing a different treatment.

4.2.3. Treatment Method

Each patient received 8 treatments and received VAS evaluation before and after each treatment. ODI evaluations were taken before the first treatment and after the 4th and 8th. Treatment frequency were 2 times per week but were adjusted according to circumstances. Other treatments such as physical therapy, drug use, cupping, or other additional treatment methods were not given simultaneously.

The goal of the treatment was to reach P/L of 3 (Tolerable pain) and ODI

<20% (Minimal disability). These measurements were only used to generate treatment numbers and thus even after patients reached those goals, they were made to continue to fulfil their 8 treatments requirement without terminating in order to verify the aspect of treatment.

4.2.3.1. Acupuncture point selection for the treatment

Acupuncture point selections were made based on published research papers about chronic LBP and the acupuncture points with the highest application frequency were selected. These points were BL23, BL24, BL25, BL40, BL60, GV3, GV4, EX21. Additionally, points that are used for blood stagnation caused by external impact, were used: tonify LU9+, SP3+, and sedeate LI11-. The point locations and their actions are displayed in Table 1.

4.2.3.2. Treatment plan

Acupuncture points based on the patient's condition were selected and according to the CNT regulation cleaned the points with alcohol wipes and needled 5mm~20mm in depth with sterile needles. First, the patient lay flat on the table in a prone position and needles were inserted perpendicularly on both sides and treated for 30min. Then the patient was positioned in a supine position and acupuncture points for blood stagnation were needled using tonifying and sedating method and treated for 30min. Acupuncture manipulation techniques of rotating and twirling, and direction of needle tip were used for LU9+, SP3+, LI11- acupuncture points.^{53,60}

Acupuncture Point	Anatomical Location	Function
ShenShu (BL23)	1.5 cun lateral to the posterior midline, on the level of the lower border of the spinous process of the 2^{nd} lumbar vertebra (L2)	Strengthens the lower back, Benefits the bones and the marrow
QiHaiShu (BL24)	1.5 cun lateral to the posterior midline, on the level of the lower border of the spinous process of the 3^{rd} lumbar vertebra (L3)	Benefits the back and strengthens the knees, Regulates and tonifies Qi and Blood of the Lower Burner
DaChangShu (BL25)	1.5 cun lateral to the posterior midline, on the level of the lower border of the spinous process of the 4 th lumbar vertebra (L4)	Strengthens the lower back , Regulates the intestines and promotes the Qi flow
WeiZhong (BL40)	In the centre of the popliteal crease, between the tendons of the biceps femoris and semitend-inosus muscles	Benefits the lower back and knees, Opens the channel and luo vessels, alleviates pain
KunLun (BL60)	In the depression on the line connecting the Achilles tendon and the highest prominence of the lateral malleolus	Opens the channel, alleviates pain, relaxes the tendons, strengthens the lumbar region
YaoYangGuan (GV3)	On the midline, below the spinous process of the 4 th lumbar vertebra	Regulates Qi in the Lower Burner, Strengthens the Original Qi
MingMen (GV4)	On the posterior midline, below the spinous process of the 2^{nd} lumbar vertebra (L2)	Tonifies Kidney Yang, warms the mingmen, benefits the lumbar region
YaoYan (Ex21)	3.5 cun lateral to the midline, on the level of the lower border of the spinous process of the 4^{th} lumbar vertebra (L4)	Opens the channel locally, Tonifie the Kidneys, strengthens the lumbar region
TaiYuan + (LU9+)	On the ventral aspect of the wrist, on the radial aspect of the radial artery & ulnar to the tendon of the abductor pollicis longus muscle	Clear the blood stagnation with SP3 and LI11
TaiBai + (SP3+)	On the medial aspect of the foot, in the depression proximal to the head of the 1st metatarsal bone, at the border of the red and white skin	Clear the blood stagnation with LU9 and LI11
QuChi – (LI11-)	With the elbow flexed, on the lateral end of the elbow crease, in a depression between the end of the crease & the lateral epicondyle of the humerus, on the extensor carpi radialis longus muscle	Clear the blood stagnation with LU9 and SP3

Table 1. Selection of Acupuncture Points

4.2.4. Measurement method

4.2.4.1. Visual Analogue Scale (VAS)

Patients marked a point in Figure 2, a visual pain measurement exam chart spanning 100mm where far left would indicate "no pain" and far right would indicate "worse pain possible", to visually show their pain level. To minimize errors, the exam chart that the patient would use to show how much pain they are feeling, did not have any gradation markings. This research utilized this exam method before and after each acupuncture treatment to measure the decline of patient's pain level.

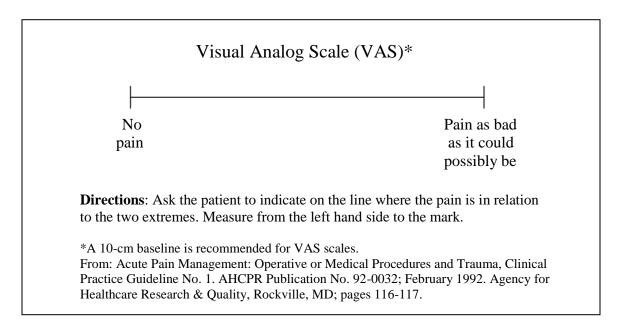


Figure 2. Visual Analog Scale

4.2.4.2. Oswestry LBP Disability Questionnaire (ODI)

The ODI aims to look into how the LBP impacts the patient's daily life and is composed of 9 questions. 9 questions regarding the current pain level, self care, raise, walk, stay seated, stay standing, sleeping, social life, and traveling are self assessed and scored. Each question can be given a point from 0 to 5 and the highest point possible is 45. Each patient's total score was divided by the number of questions they answered and converted into a percentage to use for diagnosis. Comparisons for individual questions were not converted into percentage but were evaluated as individual average for each question. ODI evaluations were conducted before the initial treatment, after the 4th treatment and after the 8th treatment.

Disability Index Score (%) =
$$\frac{\text{Patient's Score Total}}{\text{No.of sections completed x 5}} \times 100 \quad (1)$$

4.2.5. Statistical analysis

To analyze the treatment effect, VAS and ODI evaluation results were averaged and put into a (mean) \pm (standard deviation) and Statistical Program for Social Science (SPSS) V.22.0 for Windows was used for statistical analysis. The before and after treatment results of VAS and ODI were compared using paired ttest, and all statistical analysis were statistically significant at the 95% confidence level of *p* <.05. The cumulative cure rate (%) of VAS was calculated according to formula (2). The size analysis of the effectiveness was performed according to Cohen's distance (*d*) method and calculated according to the following formulas (3) and (4), and evaluated according to Table 2.

VAS cumulative cure rate (%) =

$$\frac{\text{VAS after the Nth treatment} - \text{VAS before initial treatment}}{\text{VAS before initial treatment}} \times 100 \quad (2)$$

$$d = \frac{\bar{\mathbf{x}}_1 - \bar{\mathbf{x}}_2}{s} \tag{3}$$

$$S \text{ (pooled standard deviation)} = \sqrt{\frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}} \tag{4}$$

Table 2. Description of Effect Size for the Magnitudes of Cohen's d

d	Reference
0.01	Sawilowsky, 2009
0.20	Cohen, 1988
0.50	Cohen, 1988
0.80	Cohen, 1988
1.20	Sawilowsky, 2009
2.0	Sawilowsky, 2009
	0.01 0.20 0.50 0.80 1.20

V. RESULT AND DISCUSSION

5.1. Early characteristics of research subjects

Before treatment the initial values of age, height, weight, body mass index, marriage status, occupation, smoking history, previous treatment period, compensation status, pain duration, VAS and ODI of the seven research participants were measured as shown in Table 3. The age distribution of the seven patients was between 29 and 69 years, with an average age of 54.6 years, and comprised of one male and six females. The distribution of BMI was between 21.1 and 32.0, and the mean BMI was 25.5. There was no obese patient in particular, and so it was considered that none of their LBP was due to obesity. Early duration period of physical therapy after MVA varied from 1 month to 6 months, and the average physical therapy period was 3.1 months. The duration of LBP after MVA was between 3 months and 20 months, all of whom (patients) developed chronic LBP. The average LBP period was 9.3 months. The initial VAS value ranged 5.5 to 8.6 and the mean VAS value was 7.5. The ODI% distribution was between 36% and 60%, and the average ODI% was 43.8% (Severe disability, 40 ~ 60%).

Characteristic		Score	
Mean Age (years)		54.6	
Gender	Male	1	
Gender	Female	6	
Height (inch)		63.3	
Weight (pounds)		141.9	
Body mass index		25.5	
Married/living together		4 out of 7	
Employed		4 out of 7	
Smoking		2 out of 7	
Average Period of Initial Physica Therapy (months)	al	3.1	
Litigation or Compensation beca of MVA	use	6 out of 7	
Duration of LBP (months)		9.3	
Visual analogue scale	Baseline	7.5	
Oswestry Disability Index	Baseline	43.8%	

Table 3. Baseline Characteristics of the Patients

5.2. Comparative analysis of change in VAS value

5.2.1. Analysis of VAS value before & after treatment

In order to evaluate the pain relief effect, the VAS value before and after each treatment was measured. The significance of the palliative effect is shown in Table 4, and the change in the median value is shown in Figure 3. The paired *t*-test was used as a parametric statistical method when the normality of the measured values was verified. When the normality was not recognized, the nonparametric statistic Wilcoxon Signed-rank test was applied. As shown in Table 4, the change of VAS value decreased from 7.53 ± 1.02 before the initial treatment to 1.19 ± 2.22 (p = 0.001) after the final 8th treatment, thus showed a significant treatment effect. In addition, the change of VAS value before and after each treatment proved to be significant.

No. of Tx	Before	After	Difference	<i>p</i> -value ^{a,b}
1 st	7.53±1.02	4.56±1.65	2.97±1.22	.001 ^a
2^{nd}	6.43±1.49	4.01±1.97	2.41±1.23	.027 ^b
3 rd	5.59±2.77	3.03±2.49	2.56±2.46	.033 ^a
4 th	5.43±1.72	2.90±1.92	2.53±2.10	.019 ^a
5 th	5.43±2.35	2.64±1.85	2.79±2.44	.018 ^b
6^{th}	5.61±1.91	2.36±2.10	3.26±2.40	.012 ^a
$7^{\rm th}$	4.44±1.93	1.31±1.52	3.13±2.31	.012 ^a
8^{th}	4.04±2.63	1.19 ± 2.22	2.86±2.64	.029 ^a

Table 4. Change of Pain Level in VAS before and after Acupuncture Treatment

a. paired *t*-test

b. Wilcoxon Signed-Rank test

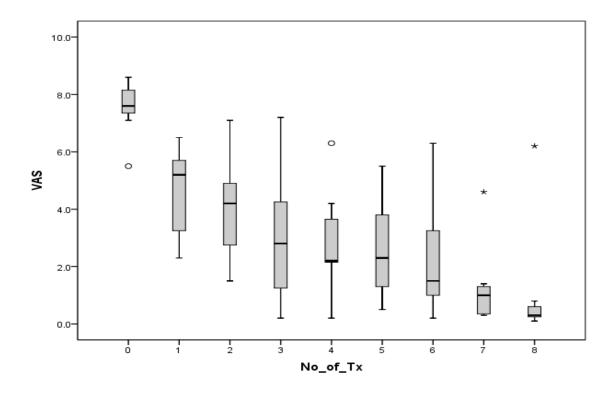


Figure 3. Box Plot of Pain Level Change in VAS before and after Acupuncture Treatment

5.2.2. Median cure rate analysis of VAS value before & after treatment

The cumulative treatment rate for VAS before and after treatment was calculated by formula (2), and the changes of the mean value and median value were shown in Figures 4 and 5, respectively. The initial treatment rate was 40.37 $\pm 17.85\%$. The cumulative treatment rate increased with the number of treatments, and the cumulative treatment rate increased to 83.46 \pm 31.35% after the final treatment of the 8th treatment (Figure 4).

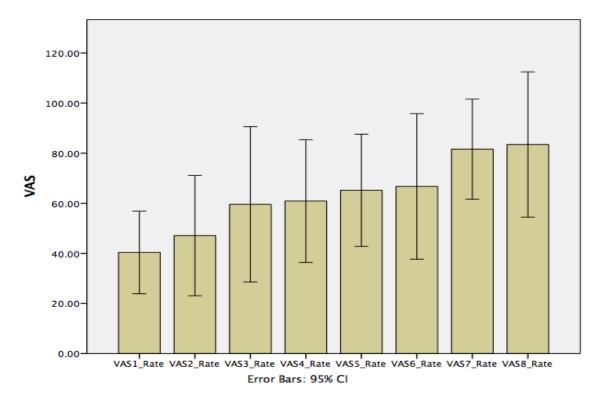


Figure 4. Treatment Rate on VAS before and after Acupuncture Treatment

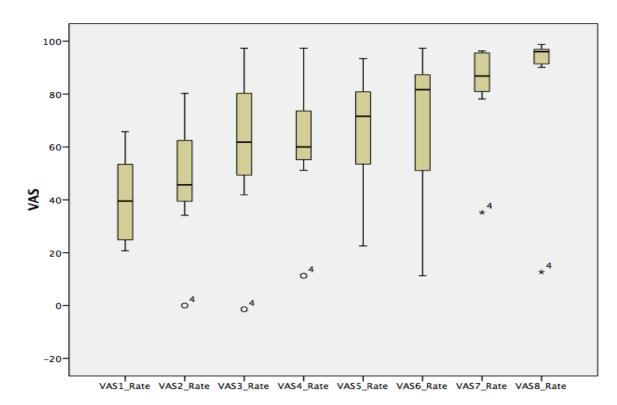


Figure 5. Box Plot of Treatment Rate on VAS before and after Acupuncture Treatment

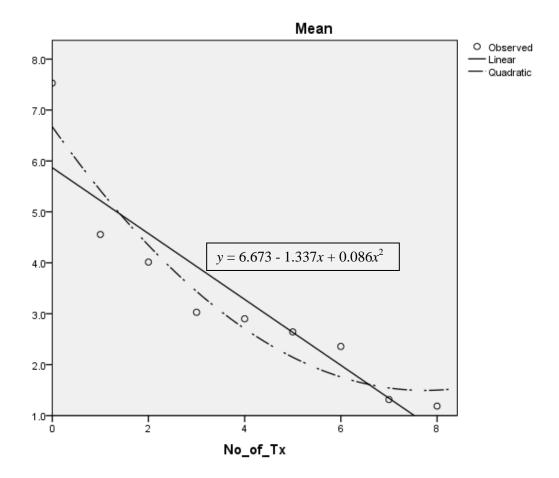
5.2.3. Size analysis of treatment effect of VAS value before & after treatment

Though the 8 acupuncture treatments showed statistical significance, the relative magnitude of those effect that would be a guide in the calculation of the number of patients in a future randomized controlled clinical trial study were calculated according to the formula (2) and (3) by Cohen's d and were evaluated according to the Sawilowsky method (Table 2). The result of s = 1.71 and d = 3.71 were analyzed to have a "Huge" effect size. The main factor is the high cure rate but it is considered that the effect size is analyzed to be huge because the standard deviation is relatively small due to the small number of patients. In addition, it was determined that the result could be including a bias because it is a comparison of the treatment effect on the initial value rather than the comparison of the treatment effect on the control group. Therefore, this is the basis for suggesting larger-scaled randomized controlled clinical trial studies.

5.2.4. Regression analysis of VAS before & after treatment

To calculate the overall treatment modality and the optimal treatment frequency, the results of regression analysis of VAS values before treatment and VAS values after each treatment are shown in Figure. 6. The variation of VAS value was found to be regressing in a quadratic equation rather than in a linear equation given that $r^2 = 0.838$ for the linear regression function and $r^2 = 0.915$ for the quadratic regression equation. The regression equation was y = 6.673 - 1.337 x $+ 0.086 x^2$. Based on this regression equation, the number of treatments to reach the goal of P/L = 3 was 4.3 treatments, which showed that five treatments were appropriate (Figure 6).

As shown in Figure 7, when the VAS value before treatment and the VAS value before each treatment were regression analyzed, it regressed in a quadratic equation rather than a linear equation. At this time, $r^2 = 0.861$, regression equation $y = 7.753 - 0.621 x + 0.024 x^2$, and the number of treatments to reach P/L = 3 was 8.3, thus it was known that 9 treatments were necessary. Therefore, we assessed the patient's pain level and other factors such as ODI, and established the basis for recommending the appropriate number of treatments between 5 and 9 treatments.



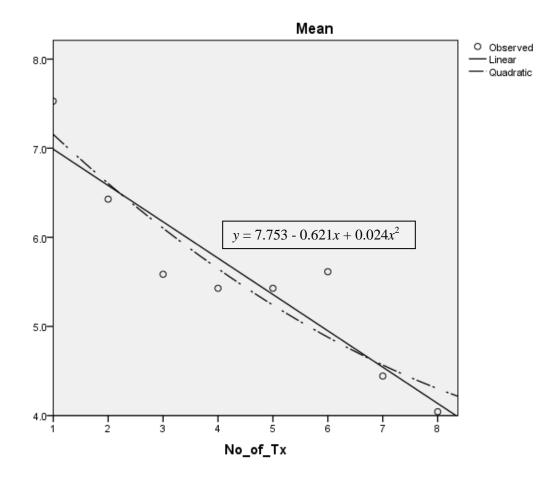
Model Summary and Parameter Estimates

Dependent Variable:Mean

Equation	Model Summary					Parameter Estimates		
	R Square F df1 df2 Sig.				Constant	b1	b2	
Linear	.838	36.249	1	7	.001	5.868	647	
Quadratic	.915	32.179	2	6	.001	6.673	-1.337	.086

The independent variable is No_of_Tx.

Figure 6. Regression Analysis of the Change of VAS After Each Treatment





Dependent Variable:Mean	
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Equation	Model Summary					Parameter Estimates		
	R Square F df1 df2 Sig.				Constant	b1	b2	
Linear	.849	33.829	1	6	.001	7.397	408	
Quadratic	.861	15.468	2	5	.007	7.753	621	.024

The independent variable is No_of_Tx.

Figure 7. Regression Analysis of the Change of VAS Before Each Treatment

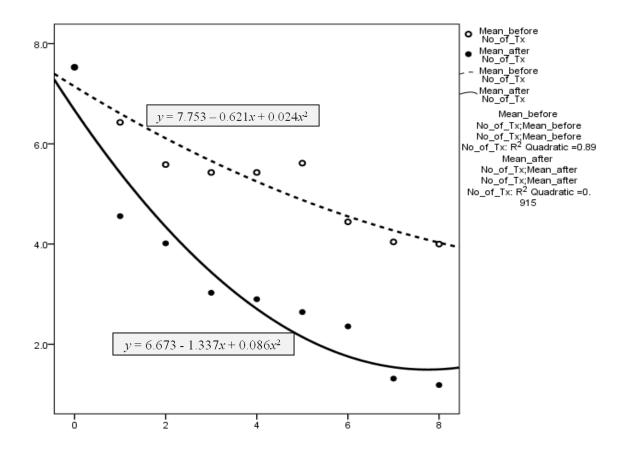


Figure 8. Regression Analysis of the Change of VAS both Before Each Treatment and After Each Treatment

5.3. Comparative analysis of ODI value change

5.3.1. Before & after treatment analysis of ODI value

As shown in Table 5 and Figure 9, the mean value of ODI% before treatment and after 8th treatment decreased from $43.9 \pm 8.0\%$ to $21.3 \pm 14.8\%$ and $22.6 \pm 16.6\%$ (p = 0.011), respectively and showed clear significant difference. On the other hand, items Q1 (degree of pain), Q3 (lifting), Q4 (walking), Q5 (sitting) and Q7 (sleep) decreased and showed that inconvenience to conduct activities directly related to pain had improved. However, it was found that the improvement in inconvenience to the more complex activities of Q2 (selfmanagement), Q6 (standing), Q8 (social life) and Q9 (travel) was insufficient. Therefore, it is suggested that patients who have chronic LBP as a sequela due to MVA should not only have their pain managed for simple movements, but also need to consider to take additional measures for activities related to everyday life and travels in their lives.

 Table 5. Change of ODI before and after Acupuncture Treatment

Questionnaire	Before 1 st Tx	After 8th Tx	Mean Difference	<i>p</i> -value
Total ODI (%)	43.9±8.0	21.3±14.8	22.6±16.6	0.011
Q1. Pain Intensity	2.7±0.5	1.0±0.8	1.7±0.8	0.001
Q2. Personal Care	1.4±1.0	0.7±1.1	0.7±1.8	0.334
Q3. Lifting	2.4±0.5	1.1±1.4	1.3±1.1	0.022
Q4. Walking	2.1±1.1	1.0±0.8	1.1±1.1	0.030
Q5. Sitting	2.1±0.4	1.0±0.8	1.1±0.9	0.015
Q6. Standing	2.3±1.3	1.6±1.3	0.7±1.6	0.283
Q7. Sleeping	2.3±1.4	0.6±0.5	1.7±1.3	0.011
Q8. Social Life	2.0±0.8	1.3±1.3	0.7±1.4	0.220
Q9. Traveling	2.3±1.0	1.3±1.1	1.0±1.5	0.134

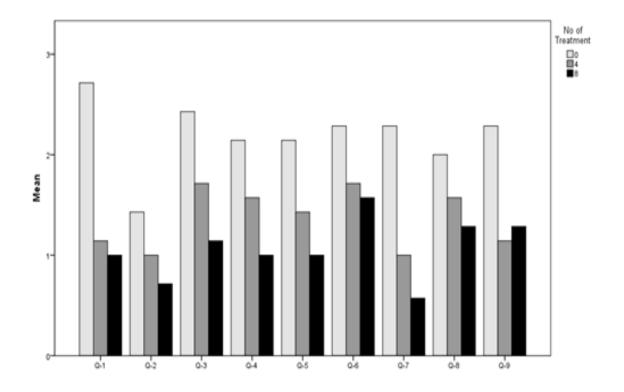


Figure 9. Change of Each Question of ODI before, after 4th and 8th Acupuncture Treatment

IV. CONCLUSION

In order to investigate the effect of acupuncture treatment on patients with chronic LBP caused by MVA, the following conclusions were drawn from a case study of clinical trial to confirm the change of pain index and change of LBP disability scale with 7 patients as subjects.

- The VAS value before treatment has decreased from 7.53 ±1.02 to 1.19 ±2.22 (p = 0.001) after treatment, and the cumulative cure rate was 83.46 ±31.35% after the 8th treatment for MVA induced chronic LBP.
- 2. In the 8 acupuncture treatments for patients with chronic LBP caused by MVA, the effect size s = 1.71, d = 3.71 and the effect size evaluated as "Huge".
- 3. In the regression analysis of the effect of the 8 acupuncture treatments on patients with chronic LBP caused by MVA, the treatment effect on the VAS value of initial treatment and after each treatment and the treatment effect on the VAS value of initial treatment and before each treatment were respectively $y = 6.673 1.337 x + 0.086 x^2$ ($r^2 = 0.915$) and $y = 7.753 0.621 x + 0.024 x^2$ ($r^2 = 0.861$), and the optimal number of treatments was 5 to 9 times.
- 4. The mean value of ODI% after 8 acupuncture treatments for patients with chronic LBP caused by MVA decreased from $43.9 \pm 8.0\%$ to $21.3 \pm 14.8\%$ ($22.6 \pm 16.6\%$,

p = 0.001). Q1, Q3, Q4, Q5 and Q7 were 2.7 ± 0.5 to 1.0 ± 0.8 (p = 0.001), 2.4 ± 0.5 to 1.1 ± 1.4 (p = 0.022) and 2.1 ± 1.1 to 1.0 ± 0.8 (p = 0.030), 2.1 ± 0.4 to 1.0 ± 0.8 (p = 0.015) and 2.3 ± 1.4 to 0.6 ± 0.5 (p = 0.011), respectively showing clear significant difference, but the Q2, Q6, Q8 and Q9 items decreased at 1.4 ± 1.0 (p = 0.334), 2.3 ± 1.3 to 1.6 ± 1.3 (p = 0.283), 2.0 ± 0.8 to 1.3 ± 1.3 (p = 0.220) and 2.3 ± 1.0 to 1.3 ± 1.1 (p = 0.134) did not show any significance.

This study has confirmed that the 8 acupuncture treatments which includes the blood stagnation prescription is useful in treating MVA derived chronic LBP patients and suggests a blind study in a much larger scale.

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Informed Consent Form

You are invited to participate in a research study about EFFECT OF ACUPUNCTURE TREATMENT ON CHRONIC LOW BACK PAIN CAUSED BY MOTOR VEHICLE ACCIDENT: CASE SERIES

The goal of this research study is to develop effective method of acupuncture treatment for the patients with chronic low back pain caused by motor vehicle accident and to provide clinical evidences for the large scaled and high quality clinical trial.

The study design is that the participants with back pain after motor vehicle accident will be selected(n=7) and evaluated using Visual Analogue Scale(VAS) and Oswestry Disability Index(ODI) test before and after treatment. The participants will be treated 8 times of acupuncture treatments.

This study is being conducted by Myungseok Song L.Ac.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic. You may change your mind later and stop participating even if you agreed earlier.

Participating in this study may not benefit you directly, but it will help to enrich the knowledge on Acupuncture and Asian Medicine.

By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your condition will not get better and that the new medicine or treatment doesn't work even as well as the old one. If, however, the medicine or treatment is not working, we will give the medication or treatment routinely offered to make you more comfortable. While the possibility of this happening is very low, you should still be aware of the possibility.

The information you will share with us if you participate in this study will be kept completely confidential to the full extent of the law. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except Myungseok Song L.Ac.

If you have any questions about this study, please contact Myungseok Song L.Ac. at 213-248-9054 (cell phone) and songusacupuncture@gmail.com. If you have any questions or concerns regarding your rights as a subject in this study, you may contact Dr. Edwin D Follick, Chair of the South Baylo University Institutional Review Board (IRB) at 714-533-6077 or edfollick@southbaylo.edu.

YOU WILL BE GIVEN A COPY OF THIS FORM WHETHER OR NOT YOU AGREE TO PARTICIPATE.

Certificate of Consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant (Print)

Name of Witness (Print)

Signature of Participant

Signature of Witness

Date: Day/Month/Year

Date: Day/Month/Year

Statement by the researcher/person taking consent:

I have accurately explained the information sheet to the potential participant. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant

Print Name Researcher (Print)

Signature of Researcher

Date: Day/Month/Year

환자동의서

이 연구에 참여하게 되는 환자는 교통사고로 인한 만성 요통 환자에 대한 침 치료 효과를 알아보기 위함입니다.

이 연구의 목적은 교통사고로 인한 만성 요통 환자에 대해 침 치료 효과를 확인하고 더 큰 규모와 양질의 시험 설계의 근거를 제공하고 위함입니다.

이 연구의 설계는 교통사고 이후 만성의 요통을 호소하는 환자들 7명을 대상으로 총 8회의 침 치료를 하고, 치료 전과 후의 통증 척도와 요통 기능 장애 지수를 측정하고 치료 결과를 분석할 것 입니다.

본 연구는 연구설계자인 한의사 송명석에 의해서만 시행 되어집니다.

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만약 귀하가 본 연구에 질문이 있다면 213-248-9054(본인 전화) 또는 songusacupuncture@gmail.com로 메일을 주십시요. 그리고 본 연구 제안서에 대해 더 궁금한 사항이 있으시다면 있으시다면 전화 (714-533-6077) 또는 edfollick@southbaylo.edu로 SBU 한의대 IRB위원회 의장인 Dr. Edwin D Follick과 연락할 수 있습니다.

YOU WILL BE GIVEN A COPY OF THIS FORM WHETHER OR NOT YOU AGREE TO PARTICIPATE.

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나는 이 연구에서 가질 수 있는 혜택과 치료과정을 선택할 수 있다는 설명을 들었고 질문할 기회를 가지며 주어진 정보를 이해하고 나의 치료 결과에 대한 정보가 연구에 사용 되어지는 것에 동의하시면 아래에 서명합니다.

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목격자 이름(Print)

참여자 서명

목격자 서명

날짜

날짜

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연구자 이름 (Print)

연구자 서명

날짜

Formulario de consentimiento informado

Usted est á invitado a participar en un estudio de investigación sobre el efecto del tratamiento de la acupuntura en el dolor lumbar crónico causado por el accidente del veh culo motorizado: CASE SERIES

El objetivo de este estudio de investigación es desarrollar un método eficaz de tratamiento de acupuntura para los pacientes de dolor lumbar crónico debido a accidentes de veh éulos de motor y proporcionar evidencias clínicas para el ensayo clínico de gran escala y de alta calidad

El diseño del estudio es que los participantes con dolor de espalda después de un accidente automovil ístico ser án seleccionados (n = 7) y evaluados mediante la Escala Analógica Visual (VAS) y la prueba del índice de discapacidad de Oswestry (ODI) antes y después del tratamiento. Los participantes ser án tratados 8 veces con tratamientos de acupuntura y el objetivo del tratamiento ser áVAS 3.

Este estudio est ásiendo realizado por Myungseok Song L.Ac.

Su participación en esta investigación es totalmente voluntaria. Es su decisión si participar o no. Si decide participar o no, todos los servicios que recibe en esta clínica continuarán y nada cambiará Si decide no participar en este proyecto de investigación, se le ofrecerá el tratamiento que se ofrece habitualmente en esta clínica. Puede cambiar de opinión más tarde y dejar de participar, incluso si acordó anteriormente.

Participar en este estudio no puede beneficiarse directamente, pero ayudar á a enriquecer los conocimientos sobre la acupuntura y la medicina asi ática.

Al participar en esta investigación es posible que usted estar á en mayor riesgo de lo que de otro modo ser á. Existe, por ejemplo, un riesgo de que su condición no mejore y que el nuevo medicamento o tratamiento no funcione tan bien como el anterior. Si, sin embargo, el medicamento o el tratamiento no est á funcionando, le daremos el medicamento o el tratamiento ofrecido rutinariamente para que se sienta más cómodo. Si bien la posibilidad de que esto suceda es muy baja, todav á debe ser consciente de la posibilidad.

La información que comparta con nosotros si participa en este estudio se mantendrá completamente confidencial en toda la extensión de la ley. La información que obtenemos de este proyecto de investigación se mantendrá confidencial. La información sobre usted que se recogerá durante la investigación será puesta a un lado y nadie, pero los investigadores podrán verla. Cualquier información sobre usted tendrá un número en ella en lugar de su nombre. Sólo los investigadores sabrán cuál es su número y bloquearemos esa información con una llave. No se compartiráni se daráa nadie excepto a Myungseok Song L.Ac.

Si tiene alguna pregunta sobre este estudio, póngase en contacto con Myungseok Song L.Ac. En 213-248-9054 (tel éfono celular) y songusacupuncture@gmail.com. Si tiene preguntas o inquietudes relacionadas con sus derechos como sujeto en este estudio, puede comunicarse con el Dr. Edwin D Follick, Presidente de la Junta de Revisión Institucional de la Universidad de South Baylo (IRB) al 714-533-6077 o edfollick@southbaylo.edu.

SE LE OFRECE UNA COPIA DE ESTE FORMULARIO SI ES O NO ACEPTA PARTICIPAR.

Certificado de consentimiento:

He le flo la información anterior, o se me ha le flo. He tenido la oportunidad de hacer preguntas al respecto y cualquier pregunta que he pedido ha sido respondida a mi satisfacción. Consiento voluntariamente a participar como participante en esta investigación.

Nombre del participante (impresi ón)

Nombre del testigo (impresión)

Firma del participante

Firma del testigo

Fecha: D á / Mes / A ño

Fecha: D á / Mes / A ño

Declaración del investigador / persona que toma el consentimiento:

He explicado con precisión la hoja de información al participante potencial. Confirmo que el participante tuvo la oportunidad de hacer preguntas sobre el estudio, y todas las preguntas hechas por el participante han sido contestadas correctamente y lo mejor de mi capacidad. Confirmo que el individuo no ha sido obligado a dar su consentimiento, y el consentimiento ha sido dado libre y voluntariamente.

Se ha proporcionado una copia de este ICF al participante

Imprimir Nombre Investigador (Imprimir)

Firma del investigador

Fecha: D á / Mes / A ño

SCORE INTERPRETATION OF THE OSWESTRY LBP DISABILITY QUESTIONNAIRE

ODI Scoring:

0% to 20% (minimal disability): Patients can cope with most activities of daily living. No treatment may be indicated except for suggestions on lifting, posture, physical fitness and diet. Patients with sedentary occupations (ex. secretaries) may experience more problems than others.

21%-40% (moderate disability): Patients may experience more pain and problems with sitting, lifting and standing. Travel and social life are more difficult. Patients may be off work. Personal care, sleeping and sexual activity may not be grossly affected. Conservative treatment may be sufficient.

41%-60% (severe disability): Pain is a primary problem for these patients, but they may also be experiencing significant problems in travel, personal care, social life, sexual activity and sleep. A detailed evaluation is appropriate.

61%-80% (crippled): Back pain has an impact on all aspects of daily living and work. Active treatment is required.

81%-100%: These patients may be bed bound or exaggerating their symptoms. Careful evaluation is recommended.

Data compiled from Fairbanks et al, 1980.