

An Evaluation of Nerve Conduction Studies and Clinical Parameters in Patients with Symptomatic Lumbar Intervertebral Disc Herniation Treated With Gabapentin

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ABSTRACT

Background: Prolapsed Intervertebral disc herniation is the most common cause of lumbar pain and radiculopathy. Diagnosis is usually made by clinical parameters, MRI, electromyography and nerve conduction study.

Objective: This research paper aimed to evaluate nerve conduction study and clinical parameters in patients with symptomatic lumbar intervertebral disc herniation treated by gabapentin.

Methodology: Thirty patients of either sex, in the age group of 18-50 years, newly diagnosed with history, physical examination and pain pattern consistent with low back ache and prolapsed intervertebral disc were included in the study. Nerve conduction study of tibial, peroneal and sural nerve was done in both lower limbs. Pain was assessed using Numeric Rating Scale (NRS 0-10), patient disability was assessed with Oswestry Disability Index (ODI) before treatment and after 2 and 6 weeks respectively. Patient satisfaction was assessed using four point scale after 2 and 6 weeks respectively. The quantitative data has been analyzed using (SPSS) version 20.0

Results: Improvement in pain in all patients following treatment with Gabapentin. The clinical parameters were statistically significant viz Numeric Rating Scale and Oswestry Disability Index. Patient satisfaction improved significantly. In our study, the variation in amplitude, latency and conduction velocity all were found to be statistically significant at the end of 6 weeks.

Conclusion: The clinical parameters and nerve conduction study both improved in patients with lumbar intervertebral disc herniation after treatment with gabapentin.

Key Words: Prolapsed intervertebral disc herniation, gabapentin, numeric rating scale, nerve conduction study, Oswestry disability index, patient satisfaction

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Estimation of the general population suffering from chronic pain of any type at a given point of time is 20%. Low back pain is an important clinical,

social, economic and public health problem. Low back pain with or without dermatomal painful lower limb radiation is a common disabling problem. It is estimated that 15 to 20% of adults present with low back pain during a single year and that 50 to 80% experience at least one episode of back pain during a life time. ^[1] Causes of low back

pain with or without radiating pain are degenerative, traumatic, inflammatory, congenital, neoplastic and gynaecological. Prolapsed intervertebral disc (PIVD) is the most common cause of lumbar pain and radiculopathy. [2] Prolapsed intervertebral disc is a collective term, describing a process in which the rupture of annular fibers allow for a displacement of nucleus pulposus within the intervertebral space, most commonly in posterior or posterolateral direction. [3] The periphery of the disc is nociceptively innervated; the degenerative and /or traumatic process of disc herniation may produce discogenic pain by the excessive mechanical strain on the outer annular fibers. PIVD can also cause radicular pain. [4]

Herniation of intervertebral disc is the commonest cause of radiculopathy. The majority of disc herniation occurs at lower three disc levels; approximately 43% occur at the level of L₅ to S₁; 47% at L₄ to L₅ and remaining 10% at the higher level predominantly at L₃ to L₄. The location of the disc herniation is important, as it will determine the clinical picture. [4]

For investigation of lumbosacral radiculopathy magnetic resonance imaging (MRI), computerised tomography (CT), electromyogram (EMG) and nerve conduction study (NCS) are very useful. Nerve conduction study (NCS) is a test of the speed of signals through a nerve. There are essentially no risks involved. A NCS test shows the condition of the best surviving nerve fibres and may remain normal in some cases. A normal NCS test result can occur in some persons with significant nerve disease. [5] Rest, physical therapy and anti inflammatory drugs are first line therapy. Non-steroidal anti inflammatory drugs (NSAIDS), centrally acting muscle relaxants, neuromodulator drugs (Gabapentin, Pregabalin) and oral steroids are the usually prescribed in patients of prolapsed intervertebral disc herniation. Gabapentin has been routinely used for the management of neuralgic pain. GABA is a principle neurotransmitter found in

inhibitory interneurons in the dorsal horn. Like GABA, gabapentin is lipophilic and therefore can cross blood brain barrier easily. It is effective and acts centrally to reduce hyperalgesia and allodynia. Gabapentin activity may involve interaction with voltage gated calcium channel. It has been shown to reduce pain in patients with chronic low back ache. The adverse effects are minimal and common being somnolence and dizziness. [6]

METHODOLOGY

The present prospective, randomized study was conducted in the Department of Physiology in collaboration with Department of Anaesthesiology and Critical Care, Pt. B.D. Sharma PGIMS, Rohtak. Ethical clearance from PG Board of studies was taken before starting the project. Thirty patients of either sex, in the age group of 18-50 years, attending Pain Clinic were enrolled in the study. Informed written consent was obtained from all the patients after explaining the procedure in detail.

Inclusion criteria:

The newly diagnosed patients with history, physical examination and pain pattern consistent with low back ache and prolapsed intervertebral disc was included in the study.

Exclusion criteria:

Patients of low back pain with causes other than prolapsed intervertebral disc like trauma, infections, strains, sprains, tumour, psychological pain, pregnancy, previous lumbar spine surgery, unstable neurological deficits and cauda equine syndrome.

Patients suffering from comorbid conditions such as diabetes mellitus, chronic renal failure, vitamin B₁₂ deficiencies, myopathy, chronic alcoholism, chronic liver disease, hypo or hyperthyroidism and cerebrovascular accidents were excluded.

Clinical Examination

All patients were subjected to detailed clinical history and physical examination in the pain clinic. The imaging studies (X-ray lumbosacral spine: anteroposterior and lateral view and MRI)

were reviewed. All the patients were subjected to routine investigation test like complete hemogram, serum electrolytes (Na⁺, K⁺), blood sugar, thyroid function test and other investigations. Numeric Rating Scale (NRS, 0-10) for assessment of pain and Oswestry low back pain disability questionnaire was explained to each patient before performing the procedure. To all the 30 patients Gabapentin alone was given in doses of 300 mg at bed time for three days and twice daily for six weeks. [7]

Nerve Conduction Study

Apparatus used: Aleron 401 model electromyography machine.

The following electrophysiological tests were performed after explaining the procedure to the patient in his/her own language, to allay the apprehension.

The basal recording of nerve conduction velocity (both sensory and motor) for tibial, peroneal and sural nerves (sensory) was done. Amplitude (mV), latency (ms) and conduction velocity (m/s) were recorded automatically by the machine and a printout was obtained. Patients were followed up at two and six weeks. On both the follow up visits, all patients underwent repeat nerve conduction study.

Pain and disability assessment

Numeric Rating Scale (NRS):- Patients were asked to sit on a chair. Patient was instructed to choose a number from 0 to 10 that best described their pain. 0 would mean 'No pain' and 10 would mean 'Worst possible pain'. [8]

The NRS was assessed and recorded at first visit and then at two and six weeks.

Oswestry Disability Index (ODI), also known as Oswestry low back pain disability questionnaire was calculated on the first visit, two and six weeks after the treatment. It gave information as to how low back pain or leg pain is affecting the patient's ability to change everyday life. [9]

Patient satisfaction was assessed at two, and six weeks on a four point scale:

1. Excellent: when the pain was completely resolved or diminished by 75% or more.

2. Good: when diminution of pain was by 50 to 74%.
3. Fair: when diminution of pain was by 25 to 49%.
4. Poor: when diminution of pain was less than 25% or there was an increase in pain.

Statistical analysis

At the end of the study data was analysed using SPSS (Statistical Packages for Social Sciences) for Windows, version 20.0 (Armonk, NY: IBM Corp). Paired t test was used to test the difference in pain score at different time intervals. One-way analysis of variance (ANOVA) was used to compare the change in pain score and patient disability (by ODI). Results were considered statistically significant if the p value was less than 0.05.

RESULT

Following observations and results were drawn from the present study:

Patient Profile

Mean age was 42.80±8.40. Majority of the patients in the two groups were in 20-50 years. 25 patients were females and 5 patients were males. Mean weight was 59.26±5.

Table1: Distribution of Age, Sex and Weight

Parameters	(n=30)
Age (years) Mean± S.D.	42.80±8.40
Weight(Kg) Mean ±S.D.	59.26±5.83
Male: Female	1:5

Measurement of Nerve Conduction Study Parameters:

Table 2: Right tibial nerve NCS comparison at different time points

Variable	Mean±SD	p-value
Amplitude at 0 weeks(baseline)	6.29±4.96	0.359*
Amplitude at 2 weeks	6.16±4.45	
Amplitude at 6 weeks	6.64±4.83	
Latency at 0 weeks(baseline)	8.72±1.19	<0.001#
Latency at 2 weeks	8.24±0.95	
Latency at 6 weeks	8.07±1.07	
Velocity at 0 weeks(baseline)	43.18±5.60	0.002
Velocity at 2 weeks	44.94±4.94	
Velocity at 6 weeks	45.70±5.03	

Repeated measures ANOVA

*All comparisons Non-Significant (NS), #All comparisons significant except 2 & 3

Table 2 depicts that there was no significant difference in amplitude of right tibial nerve when compared between 0 week and 2 weeks, between 0 week and 6 weeks and between 2 weeks and 6 weeks respectively. There was significant difference in latency when comparison was between 0 week and 2 weeks, between 0 week and 6 week while there was no significant difference when compared between 2 weeks and 6 weeks. There was a significant difference in conduction velocity when compared between 0 week and 2 weeks, between 0 week and 6 weeks and between 2 weeks and 6 weeks.

Table3: Left tibial nerve NCS comparison at different time points

Variable	Mean±SD	p-value
Amplitude at 0 weeks(baseline)	6.18±3.13	0.002*
Amplitude at 2 weeks	7.10±3.49	
Amplitude at 6 weeks	7.94±3.70	
Latency at 0 weeks(baseline)	8.87±1.30	<0.001#
Latency at 2 weeks	8.50±1.14	
Latency at 6 weeks	8.24±1.16	
Velocity at 0 weeks(baseline)	42.74±6.53	0.001@
Velocity at 2 weeks	43.86±5.67	
Velocity at 6 weeks	44.99±5.84	

Repeated measures ANOVA

*All comparisons significant except 1 & 2, #All comparisons significant except 2 & 3, @All comparisons significant except 1 & 2

Table 3 depicts that there was a significant difference in amplitude of left tibial nerve when compared between 0 week and 6 weeks, 2 weeks and 6 weeks, while there was no significant difference in amplitude of left tibial nerve when compared between 0 week and 2 weeks. There was significant decrease in latency of left tibial nerve when compared between 0 week and 2 weeks, between 0 week and 6 weeks but there was no significant difference when compared between 2 weeks and 6 weeks. There was no significant difference in conduction velocity of left tibial nerve when compared between 0 week and 2 weeks while there was significant increase when compared between 0 week and 6 weeks and between 2 weeks and 6 weeks.

Table 4 depicts that there was no significant difference in amplitude of right

peroneal nerve when compared between 0 week and 2 weeks, 0 week and 6 weeks and between 2 weeks and 6 weeks. There was significant decrease in latency of right peroneal nerve when compared between 0 week and 2 weeks, 0 weeks and 6 weeks and between 2 weeks and 6 weeks. There was significant increase in conduction velocity of right peroneal nerve when compared between 0 week and 2 weeks, between 0 week and 6 weeks and between 2 weeks and 6 weeks.

Table 4: Right peroneal nerve NCS comparison at different time points.

Variable	Mean±SD	p-value
Amplitude at 0 weeks(baseline)	2.24±2.42	0.122*
Amplitude at 2 weeks	2.64±2.39	
Amplitude at 6 weeks	2.76±2.37	
Latency at 0 weeks(baseline)	7.68±1.16	<0.001
Latency at 2 weeks	7.11±0.84	
Latency at 6 weeks	6.77±0.79	
Velocity at 0 weeks(baseline)	45.34±6.34	<0.001
Velocity at 2 weeks	48.29±5.49	
Velocity at 6 weeks	50.14±5.51	

Repeated measures ANOVA

*All comparisons Non-Significant (NS)

Table 5: Left peroneal nerve NCS comparison at different time points

Variable	Mean±SD	p-value
Amplitude at 0 weeks(baseline)	1.47±1.15	0.004*
Amplitude at 2 weeks	1.69±1.51	
Amplitude at 6 weeks	1.89±1.55	
Latency at 0 weeks(baseline)	7.70±1.03	<0.001#
Latency at 2 weeks	7.34±0.91	
Latency at 6 weeks	6.86±0.90	
Velocity at 0 weeks(baseline)	45.07±5.40	0.001
Velocity at 2 weeks	46.60±4.67	
Velocity at 6 weeks	48.51±4.71	

Repeated measures ANOVA

*Only comparison 1 & 3 significant, #All comparisons significant

Table 5 depicts that there was significant difference in amplitude of left peroneal nerve when compared between 0 week and 2 weeks and between 2 weeks and 6 weeks while there is no significant difference when compared between 0 week and 6 weeks. There was significant difference in latency when compared between 0 week and 2 weeks, 0 weeks and 6 weeks and between 2 weeks and 6 weeks. There was significant increase in conduction velocity when compared between 0 and 2 weeks, between 0 week and 6 weeks and between 2 weeks and 6 weeks.

Table 6: Right sural nerve NCS comparison at different time points

Variable	Mean±SD	p-value
Amplitude at 0 weeks(baseline)	0.67±0.76	0.261*
Amplitude at 2 weeks	0.83±0.73	
Amplitude at 6 weeks	0.94±1.02	
Latency at 0 weeks(baseline)	4.49±1.15	<0.001#
Latency at 2 weeks	3.84±0.62	
Latency at 6 weeks	3.69±0.72	
Velocity at 0 weeks(baseline)	30.28±7.45	<0.001
Velocity at 2 weeks	33.72±5.12	
Velocity at 6 weeks	35.78±5.76	

Repeated measures ANOVA

*All comparisons NS, #All comparisons significant except 2 & 3

Table 6 depicts that there was a no significant difference in amplitude of right sural nerve when compared between 0 week and 2 weeks, between 0 week and 6 weeks and between 2 weeks and 6 weeks. There was significant difference in latency of right sural nerve when compared between 0 week and 2 weeks, 0 week and 6 weeks while there was no significant difference when compared between 2 weeks and 6 weeks. There was significant difference in conduction velocity of right sural nerve when compared between 0 week and 2 weeks, 0 week and 6 weeks and between 2 weeks and 6 weeks.

Table 7: Left sural nerve NCS comparison at different time points.

Variable	Mean±SD	p-value
Amplitude at 0 weeks (baseline)	0.60±0.49	<0.001*
Amplitude at 2 weeks	1.01±1.13	
Amplitude at 6 weeks	1.02±1.19	
Latency at 0 weeks (baseline)	4.73±1.59	0.001#
Latency at 2 weeks	4.25±1.17	
Latency at 6 weeks	3.87±1.05	
Velocity at 0 weeks (baseline)	29.31±7.78	<0.001
Velocity at 2 weeks	32.43±7.99	
Velocity at 6 weeks	34.72±8.20	

Repeated measures ANOVA

*Only comparison 1 & 2 significant, #All comparisons significant except 1 & 2

Table 7 depicts that there was significant increase in amplitude of left sural nerve when compared between 0 week and 2 weeks there was no significant difference when compared between 0 week and 6 weeks and between 2 weeks and 6 weeks. There was no significant difference in latency of left sural nerve when compared between 0 week and 2 weeks while there was significant difference when compared between 0 week and 6 weeks and between 2

weeks and 6 weeks. There was significant increase in conduction velocity of left sural nerve when compared between 0 and 2 weeks, between 0 week and 6 weeks and between 2 weeks and 6 weeks.

Pain Score Numeric rating score NRS

Pain was assessed using Numeric Rating Scale (NRS 0-10). NRS was measured and recorded at following intervals 0 week i.e. before starting the treatment, 2 weeks and 6 weeks after starting the treatment respectively. Analysis of data within the group was done using one way ANOVA.

Table 8: Pain Score (Numeric Rating Scale) at Different Time Intervals.

Pain Score (NRS) at Different Time Intervals			p-value (ANOVA)
0 week(Baseline)	2 Weeks	6 Weeks	
6.36±1.73	2.83±1.14	1.63±0.55	<0.001

Mean pain score (NRS score) before starting the treatment was 6.36 ± 1.73 which decreased to 2.83 ± 1.14 after two weeks of treatment with gabapentin. Pain score was 2.83 ± 1.14 and 1.63 ± 0.55 at two and six weeks after the treatment respectively. The variation in pain score at different time intervals (i.e. at 2 weeks and 6 weeks) when compared to pain score before treatment (0 week) was clinically and statistically significant ($p < 0.001$).

Oswestry Disability Index

Oswestry disability index (ODI) was calculated before treatment (0 week) and two and six weeks after treatment (Table 9). Analysis of data within the group was done using one way ANOVA.

Table 9: ODI Score (%) at Different Time Intervals

ODI at Different Time Intervals			p-value (ANOVA)
0 week(Baseline)	2Weeks	6Weeks	
50.31±11.38	29.07±9.52	19.11±7.46	<0.001

Table 9 shows, mean ODI calculated before treatment (0 week) was $50.31\% \pm 11.38\%$ which decreased to $29.07\% \pm 9.52\%$ after two weeks of treatment with gabapentin. ODI was $29.07\% \pm 9.52\%$ and $19.11\% \pm 7.46\%$ at two and six weeks after the treatment respectively. The variation in ODI at different time intervals when compared to

ODI before treatment was statistically significant ($p < 0.001$).

Patient Satisfaction

Patient satisfaction was assessed on a four point scale:

1. Excellent: when the pain was completely resolved or diminished by 75% or more.
2. Good: when diminution of pain was by 50% to 74%.
3. Fair: when diminution of pain was 25% to 49%.
4. Poor: when diminution of pain was less than 25% or there was an increase in pain.

Patient satisfaction was assessed at two and six weeks (Table 10).

Table 10: Patient satisfaction after Treatment with Gabapentin

Parameter		
Excellent	2 week	7
	6 week	20
Good	2 week	14
	6 week	10
Fair	2 week	5
	6 week	0
Poor	2week	4
	6 week	0

Two weeks after treatment, 7 patients had excellent satisfaction, 14 patients had good satisfaction 5 patients had fair satisfaction and 4 patients had poor satisfaction. Six weeks after treatment 20 patients in had excellent satisfaction, 10 patients had good satisfaction.

DISCUSSION

Prolapsed intervertebral disc (PIVD) is the most common cause of lumbar pain & radiculopathy. [2] There are many useful diagnostic modalities but electrodiagnostic tests prove to be most useful to determine prognosis & search for other causes of neuralgic symptoms. [10] Many treatment modalities are effective in relieving chronic low back ache but lately use of neuromodulators like Gabapentin have been found to be very effective in alleviating neuropathic pain. [11]

Literature survey reveals various studies reviewing effectiveness of either

these modalities alone or comparison with NSAIDS or other neuromodulators in causing relief of chronic pain secondary to disc herniation & radiculitis. [12] We planned this study to compare & correlate the diagnostic and therapeutic modalities so as to evaluate whether nerve conduction study & clinical parameters in patients of PIVD treated with gabapentin provide a better prognostic & treatment modality or not.

PATIENT PROFILE: Table 1 depicts that all of our patients were in the age group of 18-50 years and 75% of them were females. The predominance of more number of female PIVD patients could be attributed to the cultural and socioeconomic scenario of our region. The females are taking care of agricultural work, domestic chores, animal husbandry and other physically strenuous activities. This typical age group i.e. child bearing and menopausal, predisposes women to accelerated osteoporosis and trauma.

EFFECT ON NERVE CONDUCTION PARAMETERS

Our data reveals (Table 2,3,4,5,6 &7) an improvement in nerve conduction parameters i.e. amplitude, latency and conduction velocity in all the motor and sensory nerves included in the study. Over a period of six weeks there was a subsequent increase in the amplitude and conduction velocity and decrease in the latency indicating that gabapentin is efficacious in affecting the nerve conduction parameters.

Gabapentin has been studied all over the world and has been shown to be an effective therapeutic alternative for alleviating neuropathic pain. Gabapentin being lipophilic quickly crosses the blood brain barrier and acts centrally to reduce hyperalgesia. [6]

Inhibitory effect of gabapentin on voltage gated calcium channels which send sustained afferent input to the spinal cord from the damaged nerves is believed to play a role in decreasing pain. Yildirim et al studied the effect of gabapentin in 50 patients (32 women, 18 men) with lumbosciatalgia secondary to L5 or S1

radiculopathy. Their results revealed an improved clinical picture in the group receiving oral gabapentin when compared to patients in group receiving placebo. [13] The study conducted by Backonja M et al revealed that gabapentin was effective in the treatment of painful diabetic neuropathy, postherpetic neuralgia, and other neuropathic pain syndromes. [7]

The Tables 2 to 7 compared and statistically analysed the changes in nerve conduction parameters individually for all nerves.

In our study, the variation in amplitude showed an improvement at 0, 2 and 6 weeks but was not found to be statistically significant. The decrease in latency however showed a statistically significant result between 0 and 2 weeks and 0 and 6 weeks in almost all the nerves.

The conduction velocity in all the nerves showed an increase at the end of 2 and 6 weeks and this was found to be statistically significant. All these comparisons were measured using ANOVA. The results indicate an improvement in the nerve picture in terms of changes produced by inflammation, compression or neuropathy due to PIVD.

EFFECT ON PAIN, DISABILITY AND PATIENT SATISFACTION.

The pain was assessed using NRS. Many studies have evaluated the accuracy of NRS as a screening test and it has been found that where pain screening in primary care may have substantial cost and limitations, the NRS proves to be an effective screening tool. Mean pain score (NRS score) before starting the treatment was 6.36 ± 1.73 which decreased to 2.83 ± 1.14 after two weeks of treatment with gabapentin and 1.63 ± 0.55 at the end of six weeks.

The decrease in pain score before and after treatment was found to be clinically and statistically significant; (Table 8). The pain score has been used in many studies to evaluate gabapentin as a effective therapy for improving neuropathic pain.

Similar results were obtained by Serpell, Rosenberg et al and To et al who concluded the efficacy and safety of gabapentin. [11,14,15]

The Oswestry disability index (ODI) is a 10 question survey used to assess function in people with low back and/or leg pain in which higher scores indicate greater levels of disability. [9] There was statistically and clinically significant improvement in patient disability using ODI after treatment at all time intervals during the study period. ODI had improved significantly from 50.31 ± 11.38 at 0 week to 19.11 ± 7.46 after 6 weeks of treatment with gabapentin ($p < 0.001$).

Patient satisfaction was assessed using a four point scale. Two weeks after treatment with gabapentin, 7 patients reported excellent satisfaction, 14 patients had good satisfaction, 5 patients had fair satisfaction and 4 patients had poor satisfaction showing all the different responses in four point scale. Six weeks after treatment with gabapentin, 20 patients had excellent satisfaction, 10 patients had good satisfaction.

The improvement in patient satisfaction at the end of 2 and 6 weeks study period was found to be statistically significant. Gabapentin is effective in clinical management of patients with low back pain with resultant improvement in pain scores, patient's disability and good patient satisfaction.

CONCLUSIONS

Gabapentin may be an effective neuromodulator drug in alleviating pain and disability caused by PIVD. Our study evaluated the efficacy over a short period of treatment & follow up over an extended period of at least one year would probably be a good way to analyse the long term sustained therapeutic effect of gabapentin in alleviating pain due to PIVD.

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How to cite this article: Nilabh, Beena, Malhotra N. An evaluation of nerve conduction studies and clinical parameters in patients with symptomatic lumbar intervertebral disc herniation treated with gabapentin. *Int J Health Sci Res*. 2018; 8(5):28-35.
