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Original Research Article

A prospective and observational study to assess the efficacy of pregabalin versus Gabapentin in relieving early post operative neuropathic pain with respect to clinical and functional outcomes in patients undergoing open lumbar discectomy surgery

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ABSTRACT

Background: Post-operative neuropathic pain is one of the most dreadful complications following lumbar spine surgeries. Owing to the similarities in the pathophysiological and biochemical mechanisms underlying epilepsy and neuropathic pain, many anti-epileptic drugs (AEDs) like pregabalin and gabapentin are being used in the treatment of post-operative neuropathic pain.
Methods: This prospective and observational study included a total of 60 patients out of 261 patients undergoing lumbar discectomy surgery, who postoperatively had neuropathic pain as diagnosed with LANSS score; and were randomly divided into pregabalin (n=30) and gabapentin (n=30) supplementation groups, and the efficacy was compared with respect to visual analog scale (VAS) score (clinically) and Oswestry disability index (ODI) score (functionally) at pre-operative and post-operative follow-ups; and also, total analgesia consumed.
Results: No statistical differences were observed between any of the demographic variables and surgical levels operated upon between the two groups. Both the groups showed significant improvements in clinical (VAS) and functional (ODI) outcome as compared to pre-operative status. Leeds assessment of neuropathic symptoms and signs scale (LANSS) score was significantly increased in both the groups postoperatively till the 3rdmonthfollow-up, after which there was a significant decrease in the score. The Pregabalin group showed significant ($p<0.05$) improvement in VAS and ODI scores at the post operative 1st, 3rd, and 6th month, as compared to the gabapentin group; however, at other follow-ups the difference was insignificant. Total analgesia consumed was significantly higher in the gabapentin group.
Conclusions: Our study concluded that both pregabalin and gabapentin are highly effective in the treatment of early post-operative neuropathic pain; showing encouraging clinical and functional improvements. Pregabalin had significantly better outcomes on short-term follow-ups; however, on longer follow-ups, both had similar beneficial outcomes. Pregabalin supplementation showed a significant analgesia-sparing effect as compared to gabapentin.

Keywords: AEDs, VAS, ODI, LANSS

INTRODUCTION

The common persistent symptoms found to be associated with lumbar spine surgeries in postoperative period are chronic neuropathic pain, functional limitations if any, and motor deficits.[1-5] Of these mentioned symptoms; chronic neuropathic pain is the most common debilitating symptom which affects the overall clinical and functional

outcomes of the surgery. It is very important to distinguish between nociceptive pain and neuropathic pain as the treatment modalities of both differ. Nociceptive pain in the post-operative period occurs due to an inflammatory process secondary to the soft tissue injury that happens during the surgery and is well managed with non-steroidal anti-inflammatory drugs (NSAIDs) and opioids. Neuropathic pain is the result of any lesion or dysfunction of the nervous system and has its own cellular and molecular initiative mechanisms. Such dysfunction of the nervous system may be in the form of direct injury or compression of the neural structures intra-operatively. Any injury to the nerves leads to its demyelination which subsequently causes an increase in the concentration of sodium channels around the affected area. This increase in the sodium channels evokes spontaneous discharges from the cell bodies at the dorsal root ganglion (DRG) cell level; thus, leading to pain stimuli.[6,7]

Studies have shown similarities in the pathophysiological and biochemical mechanisms underlying epilepsy and neuropathic pain. Based on these studies, an attempt was made to evaluate the efficacy of AEDs in the treatment of post-operative neuropathic pain. Pregabalin and gabapentin are AEDs that have been used for quite a long time for the treatment of chronic neuropathic pain, epilepsy, and anxiety; based on the considerations of their similar causative mechanisms.[5,6,8]

Aims and objectives

Our study aimed at diagnosing neuropathic pain and differentiating it from nociceptive one, in patients undergoing single-level lumbar discectomy, based on LANSS score; and comparing these scores as well as clinical VAS and functional ODI outcomes in patients receiving pregabalin from those receiving gabapentin for the treatment of neuropathic pain in the postoperative period.

METHODS

The present study was a prospective and observational one, conducted in the department of orthopaedics of government medical college, Nagpur from 2017 to 2020, with prior approval taken from the institutional ethical committee. The study population consisted of patients coming with low back ache due to prolapsed intervertebral disc (PIVD) at single lumbar level needing surgical decompression. There was a total of 261 patients who were diagnosed with PIVD based on clinical examination and radiological examination including standard spine X-rays and MRI. These patients were given a thorough trial of conservative management with medical treatment, physical therapy, and appropriate rest for a period of 12 weeks without success; before being selected for surgical intervention.

Inclusion criteria

Patients aged between 25-60 years of age, with radiculopathy symptoms without neuro-deficits; with X-rays showing disc space reduction and MRI showing prolapsed intervertebral disc compressing the roots with minimal degenerative changes were included in the study.

Exclusion criteria

Patients with pathological spine diseases such as spondylolisthesis, spondylolysis, tumors (primary or secondary); inflammatory or infective conditions; having a previous history of spine interventions including surgery or injections (transforaminal, epidural, facetal) for pain relief were excluded. Also, patients with severe degenerative changes seen on MRI needing instrumentation or the multilevel PIVD; or patients receiving any sort of pain modulation therapy like transcutaneous electrical nerve stimulation were excluded from the study.

All the patients underwent open lumbar discectomy surgery by the same spine surgeon team. All the patients were pre-operatively and post-operatively evaluated depending on sensory description and clinical examination as per LANSS score, and post-operative scores of ≥12 were diagnosed to be having neuropathic pain. We had 60 patients who experienced burning, shooting, or lancinating pain along with numbness post-operatively and were diagnosed to be having neuropathic pain based on the LANSS scoring system. LANSS scoring system is a simple method that has a set of questionnaires and helps to determine whether the pain is nociceptive or neuropathic depending on the response to those questions and clinical examination. The score ranges from 0 to 26, with 26 score being the most likelihood of neuropathic pain.[9] However, for practical use, recent studies have determined score of ≥12 is associated with neuropathic pain; thus, we chose the same value in our study. These 60 patients were then randomly divided into 2 groups: group A receiving pregabalin as a part of multimodal treatment and Group B receiving gabapentin as a part of multimodal treatment for pain management.

Group A (pregabalin group) (n=30) patient's dosage schedule was: day 1, 75 mg OD (75 mg/day); day 2, 75 mg bd (150 mg/day); and day 3, 75 mg TID (225 mg/day). This dose of 225 mg/day was maintained for a period of 6 months.

Group B (gabapentin group) (n=30) patient’s dosage schedule was: day 1, 300 mg OD (300 mg/day); day 2, 300 mg BD (600 mg/day); and day 3, 300 mg TDS (900 mg/day). This dose of 900 mg/day was maintained for a period of 6 months.

All the patients were given IV analgesics consisting of tramadol and diclofenac sodium for the first 3 days followed by an oral dose of diclofenac sodium 75 mg twice

daily for the next 5 days and then as and when needed. All the patients were asked to keep a record of the total number of diclofenac sodium tablets consumed for pain relief till 6 months and then excluding the initial doses (3 days of IV and 5 days of oral analgesia) that were common to both the groups; total amount consumed was calculated. Initial doses of IV for 3 days and oral for 5 days were not included in the calculations to eliminate the confounding.

All the patients were then followed up at 1st week, 1st month, 3rd month, 6th month, and 1 year post operatively. At all the follow ups LANSS score was evaluated and compared to the previous score. Clinical outcomes depending on the VAS score and functional outcomes depending on the ODI score were also evaluated at all the follow-ups. Similar to the LANSS score; VAS and ODI scores were also noted down preoperatively, to have a comparison. The total dose of analgesia consumed was also compared between the two groups.

Statistical analysis

All the data was collected in a Microsoft excel spreadsheet. The nominal data (such as gender, smoker, hypertensive, diabetic, and surgical level) was expressed as a number. The continuous data (such as age, body mass index, LANSS sores, VAS scores, ODI scores, and total analgesia dose consumed) was expressed as mean, standard deviation, and range. Comparison for significance was done by student t test (paired for intra-group and unpaired for inter-group). A $p<0.05$ was considered statistically significant.

RESULTS

The current study had a total of 60 patients whose LANSS score was found to be ≥12 on the postoperative day 1 and was then randomly divided into two groups: group A with pregabalin supplementation and group B with gabapentin supplementation in doses as mentioned above.

The average age of the population in group A was 46.71±8.3 years while in group B was 45.87±9.23 years. The difference of the two means was found to be statistically insignificant. In our study, we had a total of 24 male patients (40%) and 36 female patients (60%). Group A had 11 male and 19 female patients, while group B had 13 male and 17 female patients.

The average BMI of patients in group A was 26.97±2.64 kg/m^2 while that in group B was 27.61±3.13 kg/m^2. The difference was found to be statistically insignificant. Group A had 12 smokers while group B had 11 smokers. 14 patients in group A were diabetic, while group B had 16 diabetic patients. Group A had 12 patients suffering from hypertension, while group B had 13 hypertensive patients.

Group A had 5 patients (16%) operated on L3-4 disc, 12 patients (40%) patients operated on L4-5 disc and 13 patients (44%) operated on L5-S1 disc. Group B had 4 patients (14%) operated on L3-4 disc, 12 patients (40%) operated on L4-5, and 14 patients (46%) operated onL5-S1 disc.

No statistical differences were observed between any of the demographic variables between the two populations like age, sex, BMI, co-morbidities like diabetes and hypertension, smoking status, and surgical level (Table 1). This negates any confounding between the two groups with respect to demographic distribution and surgical levels.

The mean preoperative LANSS score of group A was 9.36±1.13, while that of group B was 9.91±1.46. The difference of the two means was found to be insignificant ($p>0.05$). The mean LANSS score of both the groups was found to increase after the surgery ≥12, thus diagnosed as suffering from neuropathic pain. The mean LANSS scores at every follow-up (1st week, 1st month, 3rd month, 6th month, and 1 year postoperatively) of both the groups are depicted in Table 2. The difference of the means of the two groups was found to be statistically significant ($p<0.05$) at the 1st, 3rd, and 6th month follow-up; while it was found to be statistically insignificant ($p>0.05$) at 1st week and 1 year follow-up. As far as the intra-group comparison is concerned, it was found that the difference was significant at all post-operative time frames with respect to pre-operative score; except at the 3rd-month follow-up, where the difference was found to be insignificant (intra-group). At 1st week and 1st month follow-ups, the scores were significantly higher while at 6th and 1-year follow-ups, the scores were significantly lower than the preoperative values.

The mean preoperative VAS score of group A was 8.23±0.95, while that of group B was 8.59±1.03. The difference of the two means was found to be insignificant ($p>0.05$). The mean VAS scores at every follow-up (1st week, 1st month, 3rd month, 6th month, and 1 year postoperatively) of both the groups are depicted in Table 3. The difference of the means of the two groups was found to be statistically significant ($p<0.05$) at the 1st, 3rd, and 6th month follow-up; while it was found to be statistically insignificant ($p>0.05$) at 1st week and one year follow-up. However, the mean VAS scores at preoperative and post-operative time frames were found to be the significantly lower ($p<0.05$) in the post-operative time frames (intra-group).

The mean preoperative ODI score of group A was 41.92±5.89, while that of group B was 42.21±6.08. The difference of the two means was found to be insignificant ($p>0.05$). The mean ODI scores at every follow-up (1st week, 1st month, 3rd month, 6th month, and 1 year postoperatively) of both the groups are depicted in Table 4. The difference of the means of the two groups was found to be statistically significant ($p<0.05$) at the 1st, 3rd, and 6th month follow-up; while it was found to be statistically insignificant ($p>0.05$) at the 1st week and one year follow-

up. However, the mean ODI scores at pre-operative and post-operative time frames were found to be significantly lower ($p<0.05$) in post-operative time frames (intra-group).

Mean amount of analgesia consumed by group A patients was 6.93±1.09 grams, while that of group B patients was 7.54±1.02 grams (Figure 1). Difference between the 2 means was found to be statistically significant ($p<0.05$).

There were 6 patients in group A and 7 patients in group B who had superficial wound infections which were treated with daily dressings and antibiotics with no further complications. The three patients in group A and four patients in group B had dural tears intraoperatively which were managed with a fat pad patch and the surgical patch with no further complications. No neurological deficits post-surgery was encountered in any of the patients. No drug-related complications/ side effects were encountered.

Table 1: Depicts the demographic distribution and surgical levels operated upon between the two groups.

Demographic data	Group A (Pregabalin), n (%)	Group B (Gabapentin), n (%)
Cases	30	30
Age (in years)	46.71±8.3	45.87±9.23
Sex (male/ female)	11 males/ 19 females	13 males / 17 females
BMI (kg/m^2)	26.97±2.64	27.61±3.13
Smoker	12 (40)	11 (37)
Diabetic	14 (47)	16 (53)
Hypertensive	12 (40)	13 (43)
Surgical level		
L3-4	5 (16)	4 (14)
L4-5	12 (40)	12 (40)
L5-S1	13 (44)	14 (46)

Table 2: Depicts the LANSS scores of the two groups at different time frames.

LANSS scores			
Time frames	**Group A, (Pregabalin)**	**Group B, (Gabapentin)**	**P value (unpaired t)**
Pre operative	9.36±1.13	9.91±1.46	>0.05
1st week post operative	15.72±1.59	16.03±1.72	>0.05
1st month post operative	11.92±1.32	12.67±1.42	<0.05
3rd month post operative	9.17±1.21	10.23±1.17	<0.05
6th month post operative	6.93±1.12	7.54±1.13	<0.05
1 year post operative	4.18±0.78	4.47±0.81	>0.05
P value (paired t)	>0.05 (3rd month)	>0.05 (3rd month)	
	<0.05 (all others)	<0.05 (all others)	

Table 3: Depicts the VAS scores of the two groups at different time frames.

Clinical outcome based on pain intensity (VAS score)			
Time frames	**Group A (Pregabalin)**	**Group B (Gabapentin)**	**P value (unpaired t)**
Pre operative	8.23±0.95	8.59±1.03	>0.05
1st week post operative	4.21±0.73	4.54±0.89	>0.05
1st month post operative	2.02±0.69	2.41±0.71	<0.05
3rd month post operative	1.21±0.61	1.62±0.65	<0.05
6th month post operative	0.98±0.42	1.26±0.49	<0.05
1 year post operative	0.67±0.32	0.82±0.37	>0.05
P value (paired t)	<0.05	<0.05	

Table 4: Depicts the ODI scores of the two groups at different time frames.

Functional outcome based on disability (ODI score)			
Time frames	**Group A (Pregabalin)**	**Group B (Gabapentin)**	**P value (unpaired t)**
Pre operative	41.92±5.89	42.21±6.08	>0.05
1st week post operative	29.42±4.23	30.13±4.12	>0.05
1st month post operative	21.36±3.63	23.64±3.47	<0.05
3rd month post operative	16.27±3.03	17.84±2.91	<0.05
6th month post operative	12.67±2.98	14.07±2.17	<0.05
1 year post operative	8.63±2.31	9.13±2.09	>0.05
P value (paired t)	<0.05	<0.05	

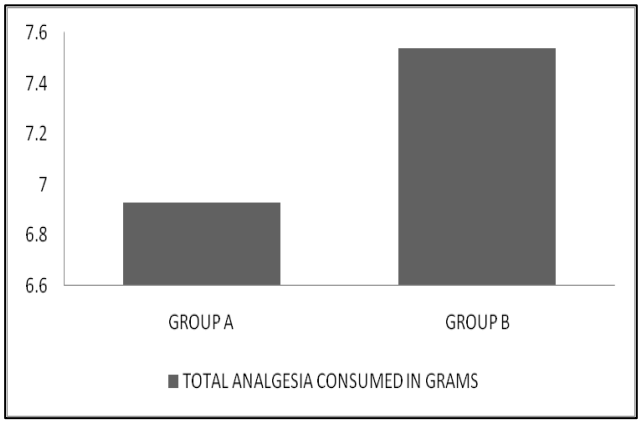

Figure 1: Depicts the total mean analgesia consumed by individual group.

DISCUSSIONS

Any damage or disease to the somatosensory system causing compression of the neural structures is the main pathophysiology behind the occurrence of neuropathic pain. This compression of the neural structures may be caused due to disc herniation or iatrogenically during the discectomy and/or fusion surgeries; which leads to demyelination of the affected nerve which subsequently causes an increase in the concentration of sodium channels around the affected area. There is also an increase in various inflammatory markers such as tumor necrosis factor (TNF), cytokines, and interleukins (IL-1 and IL-6) around the nerve which interrupts the normal function and transmission of signals across the nerves. These all factors evoke spontaneous discharges from the cell bodies at the dorsal root ganglion (DRG) cell level; thus, leading to pain stimuli. Complete transection of the nerve is associated with an increase in the release of glutamate along with other markers and activation of N-methyl-D-aspartate (NMDA) receptors, leading to allodynia.[10,11] Diagnosis of neuropathic pain is based on proper clinical, physical, and neurological examination. Patients usually present with shooting, burning pain along with tingling numbness, allodynia, and hyperalgesia.[6] LANSS scoring system is a simple method that has a set of questionnaires and helps to determine whether the pain is nociceptive or neuropathic depending on the response to those questions and clinical examination. The score ranges from 0 to 26, with 26 score being the most likelihood of neuropathic pain.[9] However, for practical use, recent studies have determined a score of ≥12 to be associated with neuropathic pain; thus we chose the same value in our study.[11]

Due to similarities in the pathophysiological and biochemical mechanisms underlying epilepsy and neuropathic pain, AEDs are being used in the treatment of post-operative neuropathic pain as well as post-herpetic neuralgia and other neuropathic pain syndromes.[12-14] Pregabalin and gabapentin are AEDs that have been used in the treatment of post-herpetic neuralgia, painful diabetic neuropathy, and other neuropathic pain syndromes including post-operativepain.[6,15-18] Various studies have shown that gabapentin in doses of 3600 mg/day has significantly reduced the suffering in various neuropathic pain syndromes when compared to placebo.[6,17,19] The study conducted by Shioe et al showed gabapentin to be effective in controlling pain and paresthesia in post-thoracic surgery patients.[20] Pregabalin has been designed to have more potent pharmacological properties than gabapentin and also have been used to increase the overall biological activity of gabapentin.[5,19,21 22] Gabapentin binds to the gamma-aminobutyric acid receptors (GABA-A and-B), while pregabalin increases the activity of glutamic acid decarboxylase activity thus increasing the neuronal levels of GABA, thus reducing the transmission of pain signals across the nerves.[23,24] A study by Gianesello et al demonstrated the analgesic and opioid dose-sparing effect of pregabalin on patients undergoing spine surgeries.[25] Various randomized clinical trials have shown analgesic doses of pregabalin to be ranging between 50 to 300 mg/day.[25-27] In a study conducted by Burke et al it was concluded that pregabalin treatment has better pain ameliorating and functional outcomes.[15]

In our study we had a total of 261 patients operated for single-level lumbar discectomy surgery; out of which 60 patients had post-operative neuropathic pain as diagnosed clinically with LANSS score ≥12. These patients were randomly divided into pregabalin (group A) and gabapentin (group B) supplementation groups. Both the groups showed significant improvement clinically (VAS scores) and functionally (ODI score) at all the follow-ups. LANSS scores in both groups showed an increasing trend postoperatively till 3rd month; after which there was a statistically significant decrease in the scores at subsequent follow-ups. We found statistically better clinical and functional outcomes in the pregabalin group at short-term follow-ups. However, at 1 year follow up the outcome in both the groups was equivocal statistically. These findings are similar to a study by Gainesello et al, where he concluded pregabalin to have adjuvant and analgesic dose-sparing effects on patients undergoing major spine surgeries.[25] We also found the total analgesia dose consumed postoperatively to be significantly less in the pregabalin group as compared to the gabapentin group.

The current study had few limitations. First, the sample size was small and the follow-up period was limited to only 1 year. Second, the only method to diagnose post-operative neuropathic pain chosen was the LANSS score, with no other supportive scale to confirm. However, there were some strengths in our study. First, all the patients included in the study were followed up for 1 year with no patient loss by the same team who were blinded regarding the supplementation as were the patients. Thus, this study was a double-blinded one. Second, due to the lack of previous studies in comparing the effective treatment role of pregabalin and gabapentin in post-operative spine patients suffering from neuropathic pain; this study can be a cornerstone for further such research. Future studies with larger sample sizes and longer follow-ups with

concentration on proper mode of administration and dosage; would help in better understanding the efficacy of these two AEDs in the treatment of post-operative neuropathic pain.

CONCLUSION

Lumbar spine surgeries are most commonly feared by patients due to post-operative neuropathic pain syndrome. Identifying this pain early and treating it accordingly, helps prevent its conversion into chronic form. Pregabalin and gabapentin are well-established AEDs being used for the treatment of post-operative neuropathic pain. However, there has been always a debate about one's supremacy over the other. Our study concluded that both these AEDs are highly and equally effective in the treatment of early post-operative neuropathic pain; with both showing encouraging clinical and functional improvements and preventing its conversion into chronic form. However, pregabalin was found to have significantly better outcomes on short-term follow-ups, both on clinical and functional grounds. However, on longer follow-ups, both have similar beneficial outcomes. Pregabalin supplementation also showed a significant analgesia-sparing effect as compared to gabapentin. However, further studies with larger sample sizes and longer follow-ups with concentration on proper mode of administration and dosage; would help in better understanding the efficacy of these two AEDs in the treatment of post-operative neuropathic pain.

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