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Original Article

Combination of caudal epidural steroids with oral gabapentin for radicular low back pain: a prospective observational study

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Abstract

Introduction: The physical, socioeconomic and psychological burden of low back pain is enormous.The poor socioeconomic condition and geographical constrains confines people to limited health facilities. The objective of the study was to evaluate whether combination of caudal epidural steroids with local anaesthetics and gabapentin is effective for radicular low back pain in the rural Nepal setting.

Methods: It was a prospective observational study including 300 patients with radicular low back pain done over a period of 6 months (13/4/2016 to 30/10/2016). All participants received caudal epidural steroid injection (6ml 2% Xylocaine with adrenaline plus Depomedroxy steroid 80mg plus 12 ml distilled water) and 200 mg gabapentin daily for three months. All patients were followed up for three months and were evaluated.

Results: Mean age of presentation was 41.21 years (SD ± 11.02) with majority of farmers (42.31%). Mean Numerical Rating Scale at the baseline was 8.01(SD±1.00) and at the first follow up was 3.98 (SD±0.83) (p <0.001). Mean Oswestry Disability Index at baseline was7.85 (SD±0.98) and at the first follow up was 4.04 (SD±0.80) (p <0.001) . Straight Leg Raising Test at baseline was less than 70° in 84.7% which improved to more than 70° in 87.9% of the patients (p-value <0.001).

Conclusion: Caudal epidural steroids combined with gabapentin is safe, economical and technically less demanding. This treatment modality can be used with good outcomes in the rural areas with limited diagnostic and therapeutic facilities.

Keywords: Caudal Epidural Steroid, Gabapentin, Numerical Rating Scale (NRS), Oswestry Disability Index (ODI), Radicular Low Back Pain (RLBP), Straight Leg Raising Test (SLRT).

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Introduction

The physical, socioeconomic, and psychological impact of low back pain is enormous.[1] Radicular low back pain is one of the most common complaint in the western part of the country. Our region being the hilly terrain, people need to carry loads on their back and climb up and down the hill to earn their livelihood.[2] The access to healthcare institutions for these people of remote highlands and plains is difficult.[3] Due to compulsions of the lifestyle the presentation of the radicular low back pain is relatively at the early age. Epidural corticosteroid injections have been reported to be used frequently in the clinical practice to treat sciatica for the last 50 years, but still its use is controversial.[4] As stated by Manchikanti et al the evidence for all three modalities of caudal injection that is caudal epidural, interlaminar epidural, and transforaminal epidural injections is good in managing disc herniation or radiculitis.[5] Although there is no proven additional benefit of local anaesthetics steroid injections commonly include a local anesthetic to avoid pain from the injection.[6] Most controlled studies have also found pharmacotherapy with gabapentinoids as an effective treatment modality for lumbosacral radicular pain.[7,8] As gabapentin prevents central sensitization, consideration should be given to prescribing this drug early in the course of sciatica.[1]

To our knowledge no published study has made the combined use of gabapentin and caudal epidural steroids for patients with low back pain with sciatica. The aim of our present study was to know the efficacy in terms of pain relief and regain of normal daily activities after three doses of caudal epidural steroid injection at an interval of one month each with low dose oral gabapentin for sciatica due to herniated nucleus pulposus.

Methods

This was a prospective observational study done in Nepalgunj Medical College Teaching hospital and Western Hospital Private Ltd. A total of 300 patients with radicular low back pain over a period of 6 months (2016/4/13 to 2016/10/31) were included in the study. This study was approved by the ethical research committee of Nepalgunj Medical College Teaching Hospital.

Considering threshold probability for rejecting the null hypothesis α(two tailed) of 0.05 (type I error), probability of failing to reject the null hypothesis under the alternative hypothesis β 0.2(type II error), effect size E 0.5, S(Δ) standard deviation of the change in the outcome of 3.0, a group size n= 283 was calculated. Considering a possible 5% dropout rate , we took a sample size of 300 patients.[9]

Inclusion criteria included age more than 18 yrs, patients of either sex, lumbosacral radicular leg pain (L5 and S1 root), with Numerical rating scale (NRS) score more than 3, duration of symptoms between 6 weeks to 12 months, straight leg raising test less than 70° and more than 30°. To make the therapy more economic and acceptable to the patients, a X-ray lumbosacral spine with or without obvious disc herniation in symptomatic patients were considered for the study. Patients who did not show any pain relief with the non-steroidal anti-inflammatory drugs were also included in the study. Exclusion criteria involved duration of pain more than 12 months, adverse reaction to study drugs, bleeding disorders and patients on anticoagulant therapy, local or systemic infection, diabetic patients, patients on psychiatric medications, drug abuse and other neurological deficit, cauda equina syndrome, pregnant patients and presence of heart disease.

Counseling the patient about the procedure and follow ups were done and written informed consent was taken. A through medical history of the patient was taken. The findings of straight leg raising test (SLRT), motor and sensory deficit, and deep tendon reflexes (DTR) were noted. NRS score and Oswestry Disability Index (ODI) score was taken at the time of presentation to make a baseline value. Pre-procedural vitals including pulse rate, blood pressure, oxygen saturation, respiratory rate and temperature were taken. Routine laboratory investigations including prothrombin time, bleeding time, clotting time and platelets were done. Random blood sugar was also done to rule out diabetes. Intravenous line was opened and pulse oximeter and non invasive blood pressure cuff was attached and the caudal epidural steroid injection was given in the prone position. The epidural steroid injection was given by trained anaesthesiologist in the minor operation theatre. Caudal space was identified by using the anatomical landmarks (Posterior superior iliac spine, sacral cornua and sacral hiatus). A 21-gauge hypodermic needle with the bevel facing ventrally was placed between the sacral cornu at an angle of 45° until contact with the sacrum was made in the “sacral triangle.” The needle was then advanced into the sacral canal by piercing the sacrococcygeal ligament by redirecting it more cephalad, horizontal, and parallel to the table. This was followed by confirmation of the epidural space by doing a negative aspiration test, then the “hoosh” test (injection of air into the caudal epidural space with simultaneous auscultation over the thoracolumbar spine), hanging drop test (a drop of injected saline staying at the Luer-lock of the needle and not getting sucked in or expressed out with other fluid. Under aseptic and antiseptic precautions 80 mg depomedrol + 6 ml 2% lignocaine+12 ml distilled water was given under monitoring. Needle advancement was done by using loss of resistance technique. A must negative aspiration of blood and CSF before injection of drug was done. Post procedure observation was done till the patient is able to walk without support with stable vitals (1 hour). Follow up of the patient was done at 1 month and at 2 months’ time from the first contact with the patient. Relief of pain was evaluated according to improvement in NRS score (0 meant no pain,1- 3 mild pain, 4-6 moderate pain,7-9 severe pain, 10 means worst pain), ODI score (as it helps to quantify subjective aspect of pain relief and improvement in normal daily activities) and SLRT

(improvement to more than 70°). Simultaneously all the patients were given oral gabapentin 100 mg BD for three months.

The primary outcome measure was taken as the relief of radicular low back pain was defined by average leg pain scores at the baseline, NRS score was used for assessment of low back and lower extremity pain which ranges from 0 (no pain) to 10 (worst pain possible). The secondary outcome measures were taken as the improvement in normal daily activities and decrease in the amount of analgesics consumed for pain. For these the ODI scoring was done to quantify the level of functional disability and consists of ten questions, each with six alternative scores ranging from 0–5.[10] The sum of the scores was expressed in percentage. A change of minimum of 20% or more than 10 points was considered a significant clinical improvement. Straight Leg raising Test was done during the physical examination to determine underlying herniated disc which was often located at L5 (fifth lumbar spinal nerve). The test is positive if the patient experiences pain when the straight leg is at an angle between 30 and 70 degrees, and a possibility of herniated disc as a cause of the pain.[11] If a patient subjectively reported improvement in pain, then second and third dose of caudal epidural steroid injection was given. If patient didn't have improvement after the first or second injection, then the patient was subjected to undergo further imaging studies (like Magnetic Resonance Imaging [MRI]). The patients were followed up for two times at an interval of one month each for second and third dose of caudal epidural steroid injection.

The success rate of pain relief was expressed as percentage. Total numbers of patients with caudal epidural steroid injection irrespective of the follow ups were included in the denominator. Data analysis was done by using software SPSS 17. For the categorical values mean values were derived and paired t- test was used to analyze improvement in NRS score and ODI score. P value of <0.05 was considered significant.

Results

Out of 300 total patients who were enrolled for the study, 17 patients had pain for more than 3 months and hence were excluded from the study. Out of remaining 283 patients, 9 patients had no pain relief after the first dose of epidural steroid injection and hence they were subjected to further investigation like MRI. Two hundred and fifteen patients had a total 3 injections (71.6%), 59 patients had total of 2 injections (19.66%) and 9 patients had single epidural steroid injection (3%). Among them 88 patients had complete pain relief (31.09%) as the NRS score was less than 2, 186 patients had partial pain relief (65.72%) and 9 patients did not have any pain relief (3.1%).

Majority of the patients presenting with radicular low back pain were farmers (42.31%). Housewives and labor account for 11.3% and 27.7% respectively. Regarding the duration of symptoms one third of the patients had Radicular Low Back Pain for 2 months (33.3%), 28% had pain for 1 month and 31.3% had pain for 3 months.

Table 1: Pain relief after caudal epidural and gabapentin.

	Frequency	Percent
No relief	9	3.2
Partial relief	186	65.7
Complete relief	88	31.1
Total	**283**	**100.0**

Mean age of the study population was 41.21 yrs (SD ± 11.05).

Out of total 300 patients 162 were male patients (54%) and 138 were female patients (46%). Mean NRS score at the base line was 8.01 (SD ± 1.00) and ODI score at the base line was 7.85 (SD ± 0.98). Mean NRS score at the first follow up was 3.98 (SD ± 0.83) with a p<0.001 and mean ODI score at the first follow up was 4.04 (SD ± 0.8) with a p<0.001. Mean NRS score at the second follow up was 3.44 (SD±0.68)with a p< 0.001 and mean ODI score at the second follow up was 3.64 (SD ±0.68) with a p<0.001. (Figure 3). The improvement in ODI score was taken as an indirect measure of regain of functional activity and improvement in the normal daily activities by the patients. Similarly, improvement in SLRT shows improvement in the functional activity of the patient due to subsidence of low back pain.

At the baseline 84.7% patients had SLRT of less than 70° but more than 30° while in the first follow up 87.9% of the patients had SLRT of more than 70° without radicular pain. In the second follow up the SLRT was further improved to more than 70° in 98.7% of the patients as shown in figure 4.

None of the patients had any complications with the combined use of caudal epidural steroids with gabapentin.

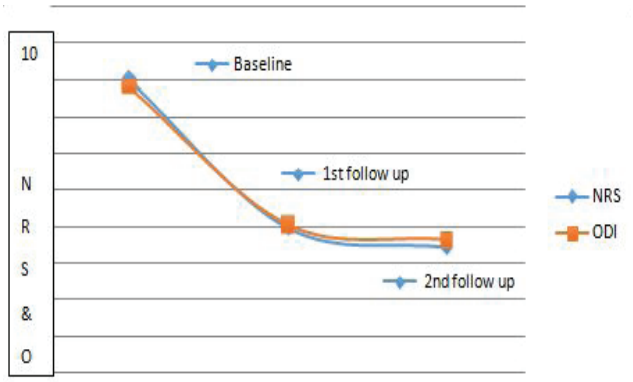

Figure 1. Improvement in NRS and ODI score on follow up after 1 months and 3 months of treatment.

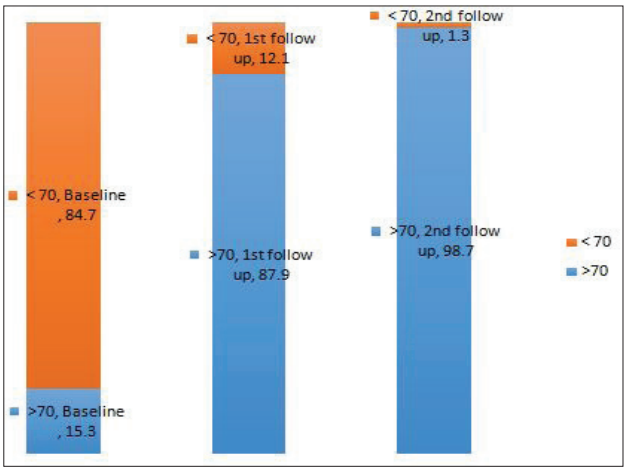

Figure 2. Improvement in SLRT after treatment on follow up. The blue column shows group of patients with SLRT > 70.

Discussion

Nepal being a developing country has its problem compounded by the occupational compulsions in rural areas of the country. This study was done in western part of the country where people do not have adequate access to the health services due to poor socioeconomic condition and lack of transportation facilities. As such we decided to provide the most economic and clinically acceptable mode of diagnosis and treatment to the patients where low back pain is the most common presenting complaint in the orthopedic outpatient department. Most of the published data had done a comparison between the two most commonly used treatments for radicular low back pain. Here we have given combination therapy of corticosteroids and gabapentin.

Epidural steroid injection has been used as an effective modality of treatment for radicular low back pain for decades. Besides many controversies it has been used widely in the treatment of radicular low back pain. As stated by Kuslich et al[12], the structures involved in the pathology of low back pain are the intervertebral discs, facet joints, ligaments, fascia, muscles, and nerve root dura. Disc prolapse was established as a major source of pain by Mixter and Barr in 1934 with their distinctive description of the herniated nucleus pulposus.[13] On the contrary, Mixter and Ayers added that radicular pain can occur without obvious cause of disc herniation.[14] Later on, pain syndromes arising from lumbar intervertebral disc without visible compression of neural structures were defined apparently by many authors.[15,16] Hence, dilemma in the pathophysiology of spinal radicular pain continues and is a subject of ongoing research and controversy. As such the discogenic pain has been accepted to play a vital role as a cause of non-specific low back pain, besides the more specific cause of disc herniation. Besides mechanical component inflammation of the compressed nerve roots has assumed an important role in the pathophysiology of radicular and discogenic pain.[17,18] Other suggested factors for neurotoxicity includes inflammatory mediators like phospholipase A2(PLA2) and tumor necrosis factor (TNFα) which are released from the degenerated disc.[19] Neural compression from the degenerated disc and vascular compromise of the nerve root also plays an important role in the pathophysiology of spinal radicular pain.[20]

In this study I have combined the two most commonly used treatment methods for radicular low back pain. Sicard in 1901 first introduced cocaine injection into the epidural space through caudal route.[21] Since then caudal epidural steroid injections have been used for treating radicular low back pain.

Besides caudal epidural injection, gabapentin is commonly used as a sole treatment or in combination with steroids for treating low back pain. Gabapentin is an endogenous neurotransmitter and is an analogue of gamma amino butyric acid(GABA). It regulates conductance of calcium through voltage gated calcium channel(VGCC) and reduces presynaptic release of excitatory neurotransmitter in the dorsal horn. It was first used as an anticonvulsant medication in 1994(33) and was also approved to be used for treating neuropathic pain conditions like neuropathic pain, diabetic neuropathy, postherpetic neuralgia, multiple sclerosis and reflex sympathetic dystrophy. Gabapentin has also been used for reducing the postoperative pain after spinal surgery, vaginal hysterectomy, abdominal hysterectomy, and laparoscopic cholecystectomy. Gabapentin binds to the α2 GABA-subunit and regulates the conductance of voltage dependent Ca2+ channels (VDCCs). It doesn't undergo GABA metabolism and doesn't interact with GABA receptor.[22]

The rationale for this prospective study is that there are more than over 50 published clinical trials comparing use of epidural steroid injections with adjuvant or placebo alone for radiculopathy[23], here we decided to combine two of the most common treatments used for low back pain with sciatica.

Our experience confirmed the beneficial efficacy of the caudal epidural steroids plus gabapentin with complete pain relief (NRS score of less than 2) in 31.09% of the patients and partial relief (NRS score between 3-6) in 65.72% of the patients as observed in the study done by Steven P Cohen et al.[23] Here we have reduced the dose of gabapentin so as to adjust for low body weight and low body surface area as the standard dose of 300mg BD caused excessive sedation in our patients.[24] In our study occupation was a major contributory factor for the radicular low back pain. Occupations like farming and carrying heavy objects on their back by laborers were deemed a major cause for disc prolapse similar to the observation in study done by V G Murakibhavi.[25] We observed that the radicular low back pain occurred in relatively young age group of patients as compared to other published studies by Samuel K et al.[26] In our study, combination of caudal epidural steroids and gabapantin have produced a significant improvement

in acute radicular low back pain similar to the results of the study done by Steven P Cohen et al.[23] Dilke *et al*[47] found statistically significant differences in terms of pain relief and return to normal daily activity in favor of the corticosteroid group which is similar to our study.[27] Further there was improvement in the SLRT from 30°-70° at the baseline to more than 70° after treatment in our study. SLRT between 30 and 70 degree suggests low back pain due to disc herniation. A negative test suggests a likely different cause for back pain. A meta-analysis reported the accuracy as sensitivity 91% and specificity 26%.[28] Our study has a limited follow up of three months for each patient during which the pain relief due to treatment was statistically significant as observed in the study done by Ridley MG et al.[29] Long term follow up with a control group would have been better to know the actual long term benefit to the patient. Besides use of MRI for the definitive diagnosis of disc prolapse would have made us easier to individualize the treatment. Manchikanti et al found that the caudal epidural steroids with or without local anaesthetics have a significant improvement in terms of NRS score and ODI in patients with disc herniation or radiculitis which supports our study.[16] On the contrary simultaneous use of other conservative modalities of treatment for low back pain is unknown in our study because the patient was discharged on the same day of injection. Besides gabapentin is very useful in treating failed back surgery syndrome after failed lumbar laminectomy[30], both of which supports the combined use of epidural steroids and gabapentin.

Conclusion

It can be concluded that caudal epidural steroids combined with gabapentin is safe, economical and technically less demanding. This treatment modality can be used with good outcomes in the rural areas where there are limited diagnostic and therapeutic facilities. It improves the functional status and decreases the severity of pain in acute condition and hence the patient can undergo physical therapy and other non surgical therapeutic modalities for pain after subsiding acute pain.

Conflict of interests

All authors have filled the ICMJE conflict of interest form and declare that they have nothing to disclose.

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