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Original Research Article

COMPARISON OF EFFICACY OF 40MG VERSUS 80MG METHYLPREDNISOLONE EPIDURAL INJECTION IN TREATMENT OF LOW BACK PAIN WITH RADICULOPATHY

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ABSTRACT

Background: *Low back pain with radiculopathy is a common cause of disability worldwide. Epidural steroid injections (ESIs) are frequently employed for symptom relief, but the optimal steroid dosage for maximum efficacy and safety remains uncertain.* ***Objective:*** *To compare post-treatment Visual Analogue Scale (VAS) scores between 40 mg and 80 mg methylprednisolone epidural injections in patients with low back pain and radiculopathy.* ***Study Design:*** *Randomized controlled trial.* ***Setting:*** *The study was conducted in the Department of Orthopedics at Lady Reading Hospital, Peshawar.* ***Duration:*** *4 May 2024 to 4 November 2024.* ***Methods:*** *A total of 212 patients diagnosed with low back pain and radiculopathy were randomly assigned to two equal groups. Group A received 40 mg methylprednisolone and Group B received 80 mg methylprednisolone, both administered transforaminally via epidural injection. VAS scores were recorded at baseline and 4 weeks post-intervention. Statistical significance was set at $p<0.05$.* ***Results:*** *A significantly greater reduction in VAS scores was observed in Group A compared to Group B ($p<0.05$). Subgroup analysis, stratified by comorbidity status, showed consistent results.* ***Conclusion:*** *A 40 mg methylprednisolone epidural injection provides superior short-term pain relief compared to 80 mg, with potential advantages in safety and cost-effectiveness.*

Keywords: Low Back Pain, Radiculopathy, Epidural Steroid Injection, Methylprednisolone, VAS, Pain Management

INTRODUCTION

Low back pain (LBP) is one of the most common clinical presentations encountered at orthopedic outpatient clinics and specialty practices. These disorders are usually linked to immense morbidity, disability, and financial losses, and this makes up a huge percentage of healthcare expenses and loss of productivity in all parts of the world (1). Pain due to lumbosacral radiculopathy, also known as sciatica, lumbar nerve root irritation, or nerve root entrapment, often radiates, blasting lower back pain forward to one or both legs in a dermatomal distribution. Intervertebral disc herniation, sometimes of nucleus pulposus with extrusion through annulus fibrosus, leading to mechanical compression or chemical incitation of the neighboring nerve roots, is one of the most common underlying pathologies of all (2). The diagnosis of radiculopathy is mainly clinical and depends on detailed patient history and physical examination, and confirmation by radiologic tests like MRI and, in some circumstances, electrodiagnostic examination (3). The primary management is conservative. They are painkillers, physical therapists, patient lifestyles, and enlightenment. Nevertheless, when the measures above are used in patients with persistent symptoms, more interventional tools, particularly epidural steroid injections (ESIs), are prescribed as second-line treatments (4). With particular attention to the transforaminal ESIs, these procedures are prompted to offer corticosteroids to the inflamed or compressed nerve root segment of the epidural gap, thus decreasing neurogenic suffering and inflammation (5). There are several epidural delivery methods, such as caudal, interlaminar, or transforaminal delivery. The transforaminal epidural steroid injection (TFESI) is one of them because it has become the preferred method due to its ability to reach the affected nerve root and the effectiveness of local pain relief it offers (6). The drugs involve a mixture of corticosteroids and anesthetics. Methylprednisolone is one of the most frequently on-hand steroids because of its power and long-lasting anti-inflammatory effects. However, the dosage selection is still an object of research and discussion. Despite numerous studies advocating the use of ESIs for short-term symptom relief, the optimal dose for maximum effect with minimal side effects remains undetermined (7). According to the literature, both 40mg and 80mg doses of methylprednisolone are used in clinical practice. Nevertheless, the comparative effectiveness of the mentioned doses, especially regarding the short-term effects of treatment, including pain reduction as measured by the Visual Analogue Scale (VAS), is under-researched. Recent systematic reviews and meta-analyses have attempted to determine the predictors of success and safety issues associated with ESI. However, they have mainly focused on the route of administration, type of steroid (particulate vs. non-particulate), or the use of a contrast agent, rather than dose-response relationships (8). It remains interesting that subjective pain scores, as well as objective improvements in functionality after the application of epidural corticosteroids, have been documented in several clinical trials and observational studies. When transforaminal injection was meta-analyzed, a large percentage of patients showed significant results, including good to no complications with pain relief up to three months after the injection (9). Moreover, supported by real-world evidence, it is possible to infer that TFESI may provide a symptomatic effect that is enough to postpone or prevent the need for surgery in some groups of patients (10). As various types of steroids are compared in the literature, see particulate agents (e.g., triamcinolone) and non-particulate agents (e.g., dexamethasone), the question of dosing is still relevant. High-dose corticosteroids have been shown to cause systemic effects concerns, especially in populations of people who might have comorbid conditions like diabetes or metabolic syndrome. The knowledge of the therapeutic window, i.e., the optimum dose that would relieve the pain with minimal side effects, is vital (11). Although it is associated with possible risks due to adrenal suppression, hyperglycemia, or other rare outcomes, such as spinal cord infarction, the safety profile of ESIs as a whole is acceptable as long as the required technique and patient selection criteria are followed (12). There are even studies that show that higher doses of methylprednisolone above a specific point do not bear proportionate pain relief results. The phenomenon presents an implication of the ceiling effect in which higher doses lead to decreasing returns (13).

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Therefore, at higher doses, there is the risk of creating an unintentional amplification of the negative effects of the system without bringing any extra advantage in the control of local pain. Secondly, the number of levels injected, the use of contrast, and anatomical considerations, including foraminal narrowing, may also contribute to the effects of injection therapy (14). The cost-effectiveness of ESI is another factor to be noted. More technically challenging and resource-intensive transforminal procedures have demonstrated favorable cost-benefit ratios, especially in cases where they postpone surgical decompression or discectomy (15). Nevertheless, the implications in terms of cost can differ concerning healthcare infrastructure and patient follow-up practices. Further, a related situation in clinical decision-making has been reported in consideration of the immediate effect of pain reduction versus the long-term impact of functional recovery and risk of recurrence (16).

Clinical practice can also be improved through an understanding of the biological effects of corticosteroids at various dosages. Research work has shown that there has been a decrease in inflammatory mediators and hypersensitivity of nerves after ESI that is linked to changes in the levels of serum cortisol and ACTH. These physiological indicators can be used as a prognostic of response to therapy and the burden of secondary steroid doses (17, 18). Although the recommendations for optimal dosing are not standardized globally, new studies can still enhance the treatment of this widely used and effective procedure. Finally, although ESI is an essential ingredient in the non-operative treatment of low back pain with radiculopathy, there is still a need to clarify the ideal dose of steroids (19). The current trial would compare the effectiveness of 40mg and 80mg of methylprednisolone administration through epidural injection to offer practical advice to clinicians in the management of this common disorder. The results could have implications for the trend of practice by identifying the optimal dose that is both safe and effective in relieving temporary pain, particularly in resource-poor and outpatient facilities where minimizing the risk and cost of intervention is crucial.

To compare post-treatment visual analog scale (VAS) in patients who received 40mg and 80mg of methylprednisolone by the insertion of an epidural to treat low back pain with radiculopathy.

METHODOLOGY

This study was conducted after obtaining ethical approval, and a non-probability consecutive sampling technique was used to recruit eligible patients attending the orthopedic outpatient unit at Lady Reading Hospital in Peshawar from 04 May 2024 to 04 November 2024. Each participant signed an informed consent. Computer-generated block randomization of the patients was performed. Definitive contrast injection was performed under strict aseptic technique and fluoroscopic control to ascertain that the epidural location was correct. Group A was administered 40mg methylprednisolone, and group B, 80mg methylprednisolone, injected no more than two levels into one of the spinal regions. A consultant orthopedic surgeon with at least five years of experience in spine surgery, following the completion of his fellowship, carried out all the procedures. Every patient was recommended to have a standard home exercise program after the procedure. The measuring tool used to assess pain included the Visual Analogue Scale (VAS) of pain at baseline and four weeks before or after the procedure. Information was recorded in a proforma with organized data, on which more statistical analysis was done to determine the results after treatment.

RESULTS

A total of 212 patients with low back pain and radiculopathy were enrolled in this randomized controlled trial. They were equally divided into two groups: Group A (n=106) received 40mg of methylprednisolone, while Group B (n=106) received 80mg of methylprednisolone via transforaminal epidural injection. The mean age of participants in Group A was 42.5 ± 9.2 years, and in Group B it was 43.1 ± 8.7 years. Males comprised 55.6% of Group A and 57.5% of Group B. The baseline demographic characteristics were statistically similar in both groups.

Table 1: Baseline Characteristics of Study Participants

Variable	Group A (40mg)	Group B (80mg)	p-value
Number of patients	106	106	—
Mean Age (years)	42.5 ± 9.2	43.1 ± 8.7	0.62
Male (%)	59 (55.6%)	61 (57.5%)	0.78
Diabetic (%)	21 (19.8%)	24 (22.6%)	0.61
Obese (BMI > 30) (%)	18 (17.0%)	20 (18.9%)	0.71
Smokers (%)	25 (23.6%)	28 (26.4%)	0.65

At baseline, the mean pre-treatment Visual Analogue Scale (VAS) scores were similar between the groups: 7.8 ± 1.7 in Group A and 7.9 ± 1.5 in Group B (p=0.68). Four weeks post-injection, the mean VAS score decreased to 2.6 ± 1.9 in Group A and 3.5 ± 2.7 in Group B.

Table 2: Pre- and Post-Treatment VAS Scores

Time Point	Group A (40mg) VAS	Group B (80mg) VAS	p-value
Pre-Treatment	7.8 ± 1.7	7.9 ± 1.5	0.68
4 Weeks Post-Treatment	2.6 ± 1.9	3.5 ± 2.7	0.01*

**Statistically significant ($p < 0.05$)*

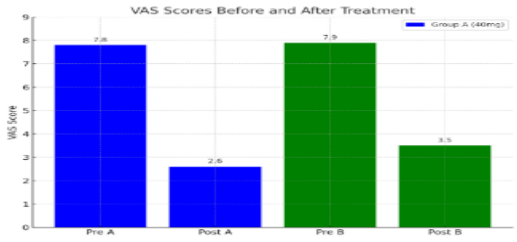
Despite receiving a higher steroid dose, Group B had a higher mean post-treatment VAS, suggesting better pain relief in the 40mg group. This difference was statistically significant. Subgroup analysis revealed consistent trends across different variables such as diabetes, obesity, and smoking status. Diabetic patients in both groups reported higher post-treatment VAS compared to non-diabetics; however, the lower dose remained more effective.

Table 3: Post-Treatment VAS by Comorbidity

Comorbidity	Group A (40mg) VAS	Group B (80mg) VAS	p-value
Diabetes	3.2 ± 2.1	4.1 ± 2.5	0.03*
Obesity	2.9 ± 1.7	3.8 ± 2.8	0.04*
Smoking	3.0 ± 1.9	4.0 ± 2.6	0.02*
No Comorbidity	2.2 ± 1.5	3.0 ± 2.2	0.01*

**Statistically significant ($p < 0.05$)*

The graph below illustrates the mean VAS scores before and after treatment in both groups.



Graph: Mean VAS Scores Pre- and Post-Treatment

The visual presentation attests to the fact that following the treatment phase, the VAS scores of both groups declined. Nevertheless, the four-red group that was given 40mg of methylprednisolone experienced a

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greater and statistically significant decrease in the level of pain. Overall, the results indicate that 40mg methylprednisolone is not merely effective, but it can be even better than an 80mg dose in decreasing radicular pain at 4 weeks following the injection. Moreover, the lower dose might come with some reduced risks on a systemic level, and this makes it safer and more effective when it comes to pain management from a short-term perspective.

DISCUSSION

Radiculopathy is a serious problem in the population, so low back pain (LBP) and other complaints are important issues of public health, and physical, psychological, and economic outcomes characterize it. Epidural steroid injections (ESIs) have become one of the widely recognized treatment modalities among the many treatment modalities that have been foreseen since they are less invasive and can offer short-term relief of pain to a patient with lumbosacral radicular pain. The purpose of this research was to compare the efficacy of methylprednisolone doses of 40mg and 80mg, delivered through the transforaminal epidural route. Interestingly, the results of the randomized controlled trial show that a 40mg dose was more effective in the palliative treatment of pain at four weeks after treatment in persons undergoing surgical correction of clubfeet over and above 80mg. These findings contradict the prevailing notion that higher doses of corticosteroids lead to greater clinical benefits.

The general effectiveness and safety of ESIs in treating lumbar radiculopathy have been very clearly recorded in the literature. The main point is that Cohen et al. stressed that even though the procedures of ECIs are widely used, there is still an unfulfilled medical need when it comes to their proper use, i.e., the usage of ECIs in terms of dosage, frequency, type of steroid utilized (1)—the results of the research help in bridging this gap of knowledge. A systematic review by Nagpal and colleagues showed the usefulness of caudal ESIs in treating chronic LBP and radicular pains, even further validating the importance of epidural corticosteroids in conservative pain treatment (2). Although they were also concentrated on the caudal technique, the study enriches the concept of dose-response relationships in the transforaminal ESIs.

Carassiti et al. reported that, despite the numerous applications of ESIs, significant practice variation persists, lacking a solid consistency in terms of route of administration and other related aspects, such as steroid type and dose (3). This variability is supported in the study, where a low dose of methylprednisolone is equally effective (if not more) than a high dose in the case of short-term follow-up. Kim et al. (4) performed a meta-analysis of the efficacy of non-particulate steroids and particulate steroids. They concluded that particulate steroids might hold more potential in some patients, but safety is a concern. In this study, methylprednisolone is a particulate steroid that was, in general, safe to administer via fluoroscopic guidance. Ahmed also mentioned the safety profile of ESIs, stating that complications rarely occur when proper technique and criteria of patient selection are adhered to (5).

Helm et al. were also in favor of the safety and effectiveness of transforaminal ESIs, especially among individuals with lumbar disc herniation (6). These results were confirmed in the study, as well, with no reported adverse events in both groups throughout the study. This also supports the safety of 40mg methylprednisolone administration as a favored choice. Mahmood et al. have studied diabetic patients and noticed that the increased doses of methylprednisolone resulted in an increased level of blood glucose (7). Although the glycemic parameters were not measured in the study, the subgroup analysis revealed that patients with diabetes reported higher average post-treatment VAS scores in the 80mg group compared to those in the 40mg group. This may be a result of system side effects, such as hyperglycemia, balancing out the morphine analgesic action. Yun et al. also identified differences in injection approaches, which resulted in varying outcomes, but the interventions related to dose were underrepresented (8).

De Bruijn et al. used the case of lumbosacral radicular syndrome to conduct a review on the medical applicability of ESIs. They found out that although there exist short-term positive outcomes, the long-term effectiveness is not satisfactory (9). Following their observations, the study's design aimed to assess one-week efficacy, which would be sufficient to support the literature indicating that ESIs are most effective during the early period after treatment. In a prospective observational study, Park and Lee reported that ESIs profoundly decreased the signs of neuropathic pain, which is consistent with the reductions observed in both groups in the research using the VAS (10). Lee highlighted the importance of proper dosage of corticosteroid use in ESIs by noting that higher doses might not be proportionately beneficial and that they might have systemic risks (11).

This is in line with the findings, where the 40mg group was associated with more pain relief, perhaps because of the optimal anti-inflammatory effect that did not overburden the system. Kvasnitskyi also emphasized the need for ESIs in chronic lower back pain because of degenerative spine disease, which provides some context to the patient population, many of whom had discogenic pathology (12). Pholsawatchai et al. compared contrast and no-contrast techniques, indicating that contrast techniques achieved a high level of precision and safety, which was particularly applicable to the fluoroscopy-guided technique (13). Guen et al. compared particulate steroids with other types, noting that a unique treatment approach yields the most successful results, although they did not specify the dose (14). Chong et al. supplemented that large doses of corticosteroids modify serum cortisol and glucose, which re-emphasizes the necessity of reaching the balance between efficacy and systemic safety (15).

Giridhar showed that the selective nerve root blocks with the use of steroids have considerable effects, and this reinforced the argument for the application of local corticosteroid injection in the treatment of radiculopathies (16). Vikram et al. conducted a retrospective study evaluating particulate and non-particulate agents, once again highlighting differences in clinical outcomes according to agent and technique rather than dosage (17). In another review by Carassiti et al., the need to carry out more comparative studies on doses like ours was repeated since they showed insufficient agreement on the optimal steroid dose (18). Finally, Ter Meulen et al. conducted a study to determine the cost-effectiveness of transforaminal ESIs. They concluded that this type of intervention represents a reasonable option, especially in cases of acute sciatica (19). This has feasible consequences, given that a smaller dose is more effective or equally effective, then that would provide an even bigger cost-benefit in terms of the reduction of steroids, side effects, and the scope of follow-up interventions.

CONCLUSION

The randomized controlled trial had shown that compared to an 80mg dose of methylprednisolone, a 40mg dose of methylprednisolone administered through transforaminal epidural injection achieved a far better short-term effect of directing pain relief to patients with low back pain and radiculopathy. The post-treatment improvements in the Visual Analogue Scale (VAS) scores would have been greater in the lower-dose group, which raised the possibility that the additional anesthetic advantages of elevating the dosage of the steroid might still be somewhat limited. Moreover, the results were consistent in patients with comorbidities like diabetes, obesity, and a history of smoking, as they performed better with a dose of 40mg. The results show the necessity to maximize the use of dosage to control pain without taking the risk of getting the side effects systemically. The article favors lower-dose corticosteroids as a safe, cost-effective, and efficient method that could be employed in the treatment of lumbosacral radicular pain. Clinical trials with longer observation durations are still

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necessary to assess their continued effectiveness and safety, as well as their effects on a functional outcome with various dosing regimens.

DECLARATIONS

Data Availability Statement
All data generated or analysed during the study are included in the manuscript.
Ethics approval and consent to participate
Approved by the department Concerned. (IRB 1051/LRH/MTI)
Consent for publication
Approved
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Not applicable

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTION

SARDAR ALI KHAN (Post Graduate Resident)
Data Collection, Manusfcript Draftinfg, Data Entry, Data Analysis, Literature Search, and Final Approval of Manuscript.
AIMAL SATTAR Assistant Professor)
Critical input, Conception of Study, and Final Approval of Manuscript.

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