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Research Article

TREATMENT OF SCIATICA BY INTERLAMINAR EPIDURAL CORTICOSTEROID INJECTIONS IN MOSUL CITY

Deena Al-samman [1]*, Nashwan Al-asaady [2]
[1]Department of Pharmacology and Toxicology, College of Pharmacy, University of Mosul / Iraq
[2]Rheumatology and Medical Rehabilitation Unit, Al-salaam Teaching Hospital / Iraq
*Corresponding Author Email: deena.saman75@uomosul.edu.iq

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ABSTRACT

Objective: This study is conducted to evaluate the effectiveness and safety of ECIs in cases of sciatica in Mosul city with the aim of pain alleviation and improving physical performance. Methods: This study was conducted at Al-Salam Teaching Hospital. Patients were well informed of ECIs therapeutic profile. Enrolled patients have sciatic symptoms for at least 3 months prior to the study, inadequately responded to conservative therapy. Patients received a mixture of Methylprednisolone injection 80mg along with Normal saline plus Bupivacaine injection. Patients assessment for lower back pain and radiculopathy on basis of NRS score. The results were categorized as excellent, moderate and poor. Results: Fifty-two patients met the criteria for inclusion, 45 were males and 7 females. Their ages 25 - 46 years. The disease duration was between 2 months to 4 years. The first symptoms at presentation were pain (100%), paresthesia (25%), radiculopathy (53%), claudication (13%) and limitation in daily activity (46%). Forty-five patients received 1 injection, 3 patients received 2 and 4 received 3 injections. Eighty seven percent of the participants achieved a statistically significant decline in NRS as compared to baseline ($P < 0.001$). Mild to moderate side effects were developed by 23% of patients immediately after injection. Excellent results were noticed in 52%, moderate in 40% and poor results reported in 8% of cases. Conclusion: ECI is extremely good option for patients with sciatica who failed to respond to conservative therapy. It is safe and effective for patients unfit for surgery, spared patient from surgery, decreases analgesic intake and allows patient to return to work early.

Keywords: Sciatica, Epidural corticosteroid injection, Interlaminar.

INTRODUCTION

Sciatica describes health condition characterized by neuropathic pain with tingling or pricking sensation going down the leg from the lower back. It could be acute (less than 4 weeks), subacute (4-12 weeks) or chronic (more than 3 months)[1,2]. In most cases, the pain resolves spontaneously by using medication and physical therapy; however, the condition tends to become chronic and intractable beside socio-economic troubles as disability and absence from work among working population[3,4].

Many epidemiological factors are thought to be involved in the development of sciatica, including, body habits, increasing body height, age, parity, genetic and particular occupation as driving[3]. Manifold etiologies play pivotal role to create pain in sciatica. Evidence advocates that the nucleus pulposus aggravate a sever inflammatory reaction in sciatic nerve roots which is a probable source of pain[5]. In addition to immune factors abnormality as well as mechanical nerve deformity. Those seem a likely combination factors for sciatica that give a sound rationale to use steroid therapy [6].

During recent years, there has been ongoing debates concerning the effectiveness and safety of epidural corticosteroids injection (ECI) against low back pain and sciatica[7]. In spite of highly controversial results of the clinical trials in this regard, ECI has become determinedly established treatment option of sciatica and other radicular pain of inflammatory origin[8,9]. It offers highly local concentration of steroids at inflamed nerve root and other region of inflammation in spinal area. As such, ECI will decrease the soft tissue swelling, edema, strain and adhesions on the nerve shaft[10]. As comparing with the newly developed transdermal disc injection, ECI has the advantages of the easiness, minimum invasion, as well as rapidly relieving of symptoms with smallest dosage requirement [11].

Like some other invasive method, ECI is associated with hazards. A comprehensive review involved 65 studies regarding ECI complication in 7315 patients observed that, ECI is a quite safe method where complications are generally infrequent and temporary[12]. Nevertheless, serious side effects occur but luckily are seldom[6,13]. Risks of ECI may be categorized as adverse effects of injected drugs, errors in the injection technique as well as neurological sequelae [14,15].

As ECIs have become an important therapeutic option and extensively practiced as part of the non-surgical treatment for sciatica in everyday medical practice. However, there is much argument about the value of ECIs. Hence, it was decided to conduct this study to evaluate their effectiveness and safety in cases of sciatica in Mosul city with the aim of alleviating the pain, improving physical performance and recovery among patients with chronic low back who need to surgery.

PATIENTS AND METHODS

This study was conducted at Rheumatology and Medical Rehabilitation Unit at Al-Salam Teaching Hospital in Mosul city, under supervision of Neurologists and Rheumatologists between March 2019 and February 2020. All patients were well informed

of the full therapeutic profile of ECI, including all risks and benefits as well as warning about the technique that might not be succeeded to relieve pain. The study protocol was approved by local hospital ethics committee. All the study participants gave written informed consent before contribution in the study.

Inclusion criteria for population of interest to be enrolled were male or female: a) age between 18 and 65 years; b) suffered from sciatic symptoms for at least 3 months prior to study; c) Numeric Pain Rating scale (NRS >4/10); d) inadequately responded to conservative therapy; e) Straight leg raising test (SLRT) between 40 and 70 degree; f) Magnetic resonance imaging (MRI) for confirmation of spinal stenosis, disc herniation or a combination of them.

Patients were excluded if: a) their ages < 18 or > 60 years; b) severe legs weakness or foot drop; c) incapable for any cause for the epidural injection; d) requiring urgent surgical intervention (cauda equina syndrome); e) spondylolisthesis; f) receiving spinal injection in the past month; g) allergy to corticosteroids; h) severe co-morbidity (infection, metabolic disease and fracture); i) pregnant or breast feeding women.

A questionnaire was designated to include the baseline measurement: age, sex, marital status, profession, work, clinical presentation, duration, medication, with all primary and secondary outcomes.

After screening and obtaining a meticulous history (concerning new or chronic co morbidity), all eligible patients had admitted to the hospital, physical and neurological examination were performed by neurologists. They included, NRS (0-10) for pain intensity of both back and leg: 0 = no pain to 10 = worst possible pain (1-3= mild pain, 4-6= moderate pain, 7-10=severe pain)[16]. SLRT which is positive if the pain was experienced when the leg was at an angle between 40° and 70°; deep tendon reflexes; examination of the motor and sensory systems of the leg muscles and lower extremities, respectively. In addition, X-Ray for Lumbo sacral spine Lateral and AP view was carried out. MRI of the lumbar spine was performed with the clinical suspicion of a disc herniation as well.

Blood sample was withdrawn from each patient for hematological tests, liver and renal function tests. In addition to blood pressure measuring.

Enrolled patient was brought to fluoroscopy room and positioned on procedure table in a lateral position. The skin above and below the injected site was sterilized by chlorhexidine and povidone iodine. Prior to epidural injection, local anaesthetia for skin with lignocaine injection (2%) was infiltrated. ECI was injected, via the interlaminar approach, by insertion a Tuohy epidural needle (16 gauge) slowly between the lamina of vertebras beneath the affected nerve. Loss of resistance test and negative aspiration technique being done at intervals. All patients received a mixture of 2ml Methylprednisolone acetate injection 80mg (Depo-Medrol, Upjohn, Belgium) along with 6ml Normal saline (0.9%) plus 6ml Bupivacaine injection (0.5%). Lastly, the needle was quickly removed, and the site of injection was dressed. After 30 minutes, patient was shifted to ward after checking for a motor or sensory block. The procedure was carried out with the assistance of anesthetist.

There were no restrictions to use painkillers. Usually, Paracetamol alone or with nonsteroidal anti-inflammatory drugs (NSAIDs) and, Opioids, if necessary, were added according to WHO-pain ladder. Additionally, gabapentin against neuropathic pain and muscle relaxants might be prescribed. Also, bed rest, physiotherapy and lumbar belts, were allowed. Information about the use of analgesics and adjuvant therapy was recorded at each visit.

For safety outcome, data was collected retrospectively from each patient after treatment, including injection related reactions, serious infections, cardiovascular effects, gastrointestinal, pulmonary, central nervous system, and dermatologic effects. All adverse events were recorded on questionnaire. According to study protocol, if side effects happened, the study participants would get a proper medical care till the symptoms resolved or be stable.

The major outcome measures were subjective pain alleviation, level of physical performance, SLRT, as well as complication. The patients were assessed for lower back pain and radiculopathy on basis of NRS score at follow-up periods, after 48 hours, at 3 months, and 6 months post therapy and compared to the pre-procedure data. At 3 months follow-up, if a patient personally reported a pain reduction, no more injection was given. However, when there was a slight decrease in pain / no improvement, a second injection was administered in the same manner with an appointment for a next follow-up after fortnight and at 4 weeks. Again, evaluation was done, and a third injection was administered, if it has been found necessary. Three injections were a maximum limit. Patient who didn't respond to even third dose of ECI were placed on the waiting list for surgery.

According to study protocol, criteria of success was achieving to pain free status for doing daily living activity effortlessly. The results were categorized as excellent, moderate and poor.

For excellent results, the criteria were considerable pain alleviation, subjective feeling of good health, unconstrained daily activity and return to the same job. Moderate results characterized by intermittent pain, subjective feeling of good health, unconstrained daily activity and change to lighter work. Poor results included no pain amelioration, assistance requiring for doing daily living activity, inability to return to work.

Statistical analysis

Data were analyzed by using SPSS (V24; IBM SPSS Statistics USA). Results were illustrated as range, mean and percentage. Responses to ECI at 48hours, 3 months and 6 months post therapy were compared with baseline. Normality for data distribution was evaluated by Shapiro-Wilko test. Student t-test was used for testing differences between means when data followed normal distribution, or Mann-Whitney test. Probability values ≤ 0.05 were considered statistically significant.

RESULTS

A total of 52 patients met the criteria for inclusion in this study; Of whom, 45(86.5%) were males and 7(13.5%) were females. Their ages ranging 25 - 46 years and mean of 36 years. The disease duration was between 2 months to 4 years (mean 1.8 years). Eleven male (21%) patients were manual laboring and 34(65%) non-manual workers. While all the 7 females (14%) were housewives. Regarding the diagnosis, disc prolapsed was seen in 33, spinal stenosis in 7, while a combination of both in 12. The first symptoms at presentation were pain (100%), inability to walk properly (23%), paresthesia and numbness (25%), radiculopathy (53%), decreased muscle force (13%), sensory deficit (10%), claudication (13%) and limitation in daily activity (46%) (Table 1).

Table 1. Demographic characteristics of enrolled patients prior to intervention (N=52)

Characteristic	Result: N (%)
Sex distribution:	
Male	45(86.5)
Female	7 (13.5)
Age(years): range(mean)	25 – 46 (36)
Duration of symptoms (mean / years)	1.8
Occupation (%):	
Manual worker	21(11)
Non-manual worker	34(65)
Housewives	14 (7)
Diagnostic:	
Disc prolapse	33(64)
Stenosis	7 (13)
Combination (Disc + stenosis)	12(23)
First symptoms at presentation:	
Pain	52(100)
Inability to walk properly	12(23)
Paresthesia and numbness	13(25)
Radiculopathy	
- right side	12(23)
- left side	9 (17)
- bilateral	7 (13)
Decreased muscle force	7 (13)
Sensory deficit	5 (10)
Claudication	7 (13)
Limitation in daily activity	24(46)

A total of 63 ECI were given to 52 patients. Of those, 45 patients received one injection only, 3 patients received 2 and 4 patients received 3 injections. Duration between ECI 1 and ECI 2 was 3 months, but the duration between ECI 2 and ECI 3 was 1 month. The vast majority of ECIs (71%) were injected at L5-S1 level, 23% at L4- L5 level, and only 6% at level L3-L4 (Table 2).

Table 2: The site of lumber epidural injection (N=52)

Site of Injection	Number of Patients	Percentage
L3-L4	3	6%
L4-L5	12	23%
L5-S1	37	71%

Generally, pain and paresthesia significantly improved as subjectively evaluated by the patients. Of the 52 participants, 45 patients got significant improvement in symptoms.

After first ECI, pain relief was reported by 28 patients (54%) within the first week. While 11 patients (21%) reported pain relief within the second week and 11 patients (21%) after 4 weeks. However, recurrence of pain after relief was reported by 5 patients after 3 months of ECI. No response at all was notified by 2 patients (4%) (Table 3). The range of pain relief duration was between 2 days to 3 months (mean 22 days).

Table 3: Duration of pain relief after ECI

Duration of Pain Relief	Number of Patients	Percentage (%)
48 hr – 7days	28	54%
8 days – 14 days	11	21%
15 days - 3 months	11	21%
No response at all	2	4%

In this study, NRS was the main efficacy outcome measure for evaluation of the treatment effectiveness. It was evaluated at baseline and repeated at 48 hours, 3 months, and 6 months post therapy. At base line, thirteen patients had moderate pain ((NRS 4-6), 39 patients had severe pain (NRS 7-10). After 48 hours, it was found that 27 patients had mild pain (NRS 1-3), 22 patients with moderate pain and 3 patients continued to have severe pain. After 3 months it was found 14 patients to be with mild pain, 33 patients with moderate pain and 5 patients with severe pain. After 6 months, 8 patients had mild pain, 40 patients with moderate pain and 4 patients had severe pain. It was noticed that the effect of ECIs decreases with time.

Eighty seven percent of the 52 participants achieved a statistically significant decline in NRS scores as compared to baseline over the time ($P < 0.001$). It was higher at the baseline (8.7) compared to its values 5.4 after 48 hours, 6.6 and 5.5 at 3 months and 6 months respectively. The percentages of improvement of NRS from baseline were 38%, 24% and 37% respectively (Table 4,5).

Table 4: Numeric Pain Rating Scores (NRS) before and after ECI (N=52)

Time	Score										Mean
	1	2	3	4	5	6	7	8	9	10	
Baseline	⁄	⁄	⁄	⁄	5	8	9	18	8	4	8.7
After 48 hrs	⁄	15	12	11	10	1	1	⁄	2	⁄	5.4
3 months	⁄	7	7	14	11	8	1	⁄	4	⁄	6.6
6 months	⁄	3	5	12	13	15	2	⁄	2	⁄	5.5

Table 5: Pre and postoperative assessments of NRS with the percentages of pain improvement after ECI. Data are mean (range) (%), N=52

Outcome Mean (Range)	Baseline	48 hours/ Improvement (%)	3 months / Improvement (%)	6 months/ Improvement (%)
NRS (0 – 10)	8.7(5-10)	5.4*(2- 9) 38%	6.6*(2- 9) 24%	5.5*(2-9) 37%

*P <0.0001

For SLRT test, positive result was elicited in 49(94%) patients (Positive test is between 40° -70°) (Table 6).

Table 6: Straight leg raising test (SLRT) before and after ECI (N=52)

Time	Unilateral SLRT 40° - 70°	Bilateral SLRT 40° - 70°	Total
Baseline	14	9	23
After 48 hrs	5	2	7
3 months	4	4	8
6 months	7	4	11

Regarding safety concerns, 12 patients (23%) developed side effects immediately after injection. These reactions were mild to moderate in severity. Mostly (75%) were accidental intra-dural punctures (headache, vomiting and drowsiness) that subsided with conservative management, as bed rest, oral rehydration fluids and analgesics. Elevated blood pressure was reported in 2 cases. While skin discoloration with local pain at the injection site was noticed in 1 patient (2%) (Table 7). However, neither infections were noticed during the period of study nor mortality was related to this outcome.

Table 7: Summary of the adverse effects of ECI (N=52)

Adverse events	Number of patients (%)
Total number of patients with AE	12(23)
Headache	7(13.5)
Vomiting	1(2)
Drowsiness	1(2)
Elevated blood pressure	2(4)
Localized increase in pain with skin discoloration	1(2)

Additional therapy was prescribed during the first week post operation including, muscle relaxants in 40 patients (77%), NSAIDs and/or Opioids in 36 cases (69%) and gabapentin in 6 cases (12%). Those who partially responded, physical therapy was offered.

In our study, excellent results were noticed in 27(52%), moderate in 21(40%) and poor results reported in 4 cases (8%). Furthermore, at 3 months, 76% of the patients recovered from pain and they had the ability to do daily living activity freely as well as return to work. They were satisfactory with the treatment. However, 4 patients (8%) exhibited no relief after three ECI necessitated surgical treatment.

DISCUSSION

To the best of our knowledge, this is the first study in Mosul City/Iraq that used ECIs to assess the response of patients with sciatica. Even though the comparison among variety of clinical studies is difficult and not always possible with respect to differences in patients demographics, duration of symptom before treatment, patient's interpretation of pain intensity and differences in patients follow doctors instructions post injection. Moreover, type and dosage of the steroid used, volume and route of injection, number of injections as well as management plans are other confounding variables[16,17]. The findings of the present study are very encouraging. ECI was generally well tolerated by the most patients. In addition to being less invasive procedure, is effective intervention in ameliorating symptoms in patients of low back pain and sciatica and associated with less morbidity and mortality.

The results of the present study prove that ECI is an important therapeutic option for treatment of patient with sciatica who fails to respond to other therapy. Excellent to moderate response was observed in 92% of participants, while 8% were with poor results during 6 - month period. This observation is in a accordance with the results of Loy`s study that reported an excellent to good pain alleviation in 93.35% of epidural treated cases[11].

NRS was the main efficacy outcome measure for evaluation of the treatment effectiveness in this study. ECI has been shown to be successful in suppressing pain as indicated by a significant dropping in the mean NRS from baseline by -3.3 after 48 hours ($P < 0.001$), by -2.1 ($P < 0.001$) and -3.2 ($P < 0.001$) at 3 and 6 months respectively. NRS was also used previously by Madhukar et al.[16]

Although, inconsistent results were shown by many studies about the efficacy of ECI. Yet, there was a trend for temporal improvement in symptoms and acceleration of the recovery rate[18]. However, we noticed that the success rate relies on the duration of disease. In our study, four patients, with chronic low back pain for more than one year, did not respond to ECIs and referred for surgery. This observation is in accordance with the studies carried out by Sharma S et al and Blankenbaker et al who concluded that the success rate depended on the back-pain duration.[19,20]

ECI is a cocktail containing long acting steroid plus epidural anesthetic substance along with normal saline [21,22]. Its mode of action is not well understood yet.

For corticosteroid, it appears to play a vital role in pain alleviation in these patients. The proposed theories of steroid action are inhibition of neuropeptide synthesis, anti-inflammatory and stabilization of the membrane with some anesthetic effect that decreases sensory symptoms[16]. So that, ECI provides analgesia for a variable duration during which the patient be able to practice rehabilitation exercises[23]. Methyl prednisolone was used in this study for its anti-inflammatory effects and for its long acting duration[24]. Moreover, it was found that the existence of methyl prednisolone in epidural gap suppresses transmission in unmyelinated C fibres, the major nociceptive pathway[25].

Whereas, epidural anesthetic acts by blocking the spinal nerve so reduces the local and referred pain in sciatica. The effect of anesthetics persisting for a few weeks and might outlast the normal duration of a local anesthetic[26].Thus corticosteroid with local anesthetic were utilized in this study to achieve longer success. Normal saline is used to expand the potential epidural space and thus the pressure effect of herniated nucleus on nerve roots reduced[28].

Generally, ECIs are administrated by three routes; interlaminar, transforaminal and caudal approach. Interlaminar approach is easy for both doctor and patient as well as release the drug closer to the injured site[29]; Therefore, this route was selected for our participants.

With regard to the volume of injection, it is usually 1-5ml. Some authors reported that the volume of injection should not be < 4ml[7]. In Valat et al. study, the volume of injection was too small (2ml) that might be insufficient[17]. On the other hand, the volume of 8 ml in Carette et al. study didn't report additional efficacy. However, Botwin et al. found that using a large volume of injection aids in washing out the inflammatory mediators and breaks up the adhesions[31]. For this reason, the volume injected in our study was 14ml.

The ideal number of ECIs has not been defined yet. It has been reported that the effect of local corticosteroids lasts for at least 2-3 weeks at therapeutic level. For this reason, many clinicians have recommended multiple injections[17]. McQuay and Moore have found that ECIs were providing relief for about 12 weeks[32].

Although the effect of ECIs declines with time, a few patients had no pain recurrence during their lifetime after first ECI[11]. While some patients get better only after two or sometimes three injections. But it is not likely that rising the number of injections more than 3 gives any extra benefits[33]. In the present study, 86% of patients received only one injection, 6% of the patients received 2 and 8% of the patients received 3 injections. Also, the adequate period between 2 injections is debatable yet. In France, three ECIs at 2-day intervals are recommended for treatment of sciatica[34]. Some studies demonstrated that 7 to 10 days interval was appropriate[35]. While in other study the range of interval between first and second injection was 5-32 days (average, 21days) and 19-27 days (average, 23 days) was between second and third injection[25]. In this study, the duration between the first and the second ECI was 3 months, and the duration between the second and the third injection was 1 month. Patients who were not responding to even 3 ECIs were considered for surgery.

Interestingly, this type of management provides pain-free period which enables the patient for physio-therapy that aids in early recovery. In addition, it reduces the time of bed rest, the need for analgesics and allows earlier returning to work. So that, additional therapy was prescribed only during the first week post operation. At 3 months, 76% of the patients recovered from pain and they have the ability to do daily living activity freely as well as return to work.

With regards to safety concerns, this kind of therapy has more advantages than systemic therapy, as local injection ensuring higher drug concentrations to the affected area and lowering the systemic side effects like endocrine suppression, hyperglycemia as well as negative effect on bone metabolism[36]. However, ECIs can be dangerous if not performed carefully according to the imposed strict protocol during operation[21]. Both minor side effects and major complications have been reported by many previous studies[17,21,37]. Needle placement, steroid or chemical constituents used in the injection formulation, might be responsible for these complications[3,16]. However, in our study, ECIs were generally well compatible by most participants. Worrisome and severe complications that were reported in other articles have not been seen[38]. Headache, vomiting, drowsiness and local pain at the injection site, were the main adverse effects observed. All of these events were mild and transient and subsided with conservative therapy. These observations is agree with other studies carried out by Madhukar et al, Gul et al and Runu et al[16,24,25].

Importantly, fluoroscopy was used in this study in order to control the injection site and to improve its positive results. However, it was not used by Valat et al[17].

Of notice, most physicians firmly convinced that ECIs are important in the management of sciatica. This opinion relying on judgments of experts. Furthermore, it is reinforced by vastly uses of ECIs for more than 50s years and still being used internationally. Therefore, it is difficult to regard that the lack of efficacy could have been overlooked throughout several years by so many clinicians[28]. There is controversy about the ability of ECI to reduce the need for operation in patients with symptoms that are severe enough to be considered for surgical intervention[1,28]. Although the treatment of sciatica with ECIs is by no mean a permanent therapy and their effects decrease with time. However, some patients had no recurrences during their lifetime11. As we demonstrated from our study, ECIs didn't affect the ultimate need to surgery for these patients, but ultimately, they spared patient from surgery. Particularly, patients who unfit for surgery like, very young patient for a sophisticated neurosurgery or patients of severe co morbidities[21]. This demonstration is in consistence with previous observation of Tufan et al that confirmed the surgery-sparing effect of ECI[21]. Also, Schaufele et al noted the low incidence of subsequent surgery in patients receiving ECIs in a controlled study for 5 years follow up[39].

CONCLUSION

The observations of this study prove that ECI is extremely good option for management of patient with sciatica who failed to respond to conservative therapy. ECI is safe and effective non-surgical method for patients unfit for surgery like, co-morbidities, severe clinical symptoms or very young for a complicated spinal surgery. It is well tolerated by patient without reporting major side effects, spared patient from surgery, decreases analgesic intake and allows patient to return to work early.

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