

EPIDURAL STEROID INJECTION IN HERNIATED DISC AND LUMBAR CANAL STENOSIS: IS IT JUST A PLACEBO?

INJEÇÃO EPIDURAL DE ESTEROIDES EM HÉRNIA DE DISCO E ESTENOSE DO CANAL LOMBAR: É APENAS UM PLACEBO?

INYECCIÓN EPIDURAL DE ESTEROIDES EN HERNIA DE DISCO Y ESTENOSIS DEL CANAL LUMBAR: ¿ES SOLO UN PLACEBO?

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ABSTRACT

Objective: To study the role of epidural steroid injection (ESI) in patients with lumbar disc herniation (LDH) and lumbar canal stenosis (LCS). ESIs are regularly used to support non-operative treatment for LBP, and our anecdotal impression is that a considerable proportion of patients report substantial pain relief after ESI. **Methods:** One thousand consecutive patients (645 patients with LDH and 355 patients with LCS) who required ESI from January-August 2018 were included. All were given the same ESI, prepared with triamcinolone (80 mg), bupivacaine (0.25%, 4 ml) and normal saline (4 ml). Patients were evaluated using the numerical rating scale (NRS) immediately after the injection, after 7 days, and after 3 months. **Results:** The mean NRS back-pain score of the LDH-group was reduced from 5 (range: 4-8) to 4 (range: 2-7) immediately after injection, 2 (range: 1-7) after 7 days and 2 (range: 1-7) after 3 months (p-value < 0.001). The mean NRS back-pain score of the LCS-group was reduced from 5 (range: 4-8) to 4 (range: 2-7) immediately after injection, 2 (range: 1-7) after 7 days and 3 (range: 1-7) after 3 months (p-value < 0.001). The mean NRS leg-pain score of the LDH group was reduced from 5 (range: 4-9) to 3 (range: 3-7) immediately after injection, 1 (range: 1-6) after 7 days and 2 (range: 1-7) after 3 months (p-value < 0.001). The mean NRS leg-pain score of the LCS group was reduced from 5 (range: 4-9) to 4 (range: 3-7) immediately after injection, 3 (range: 1-7) after 7 days and 2 (range 1-6) after 3 months (p-value < 0.001). **Conclusion:** ESI causes statistically significant improvement in back and leg pain in patients with LDH and LCS. However, the short and medium-term efficacy of ESI in the LCS group was lower than in the LDH group. **Level of evidence IV; Prospective hospital-based study.**

Keywords: Back Pain; Hernia; Spinal Stenosis.

RESUMO

Objetivo: Estudar o papel da injeção epidural de esteroides (IEE) em pacientes com hérnia de disco lombar (HDL) e estenose do canal lombar (ECL). As IEEs são usadas regularmente para dar suporte ao tratamento não cirúrgico da dor lombar e nossa impressão empírica é que uma proporção considerável de pacientes relata alívio substancial da dor depois da IEE. **Métodos:** Foram incluídos mil pacientes consecutivos (645 pacientes com HDL e 355 pacientes com ECL) que precisaram de IEE de janeiro a agosto de 2018. Todos receberam a mesma IEE preparada com triamcinolona (80 mg), bupivacaína (0,25% 4 ml) e solução salina normal (4 ml). Os pacientes foram avaliados pela Escala de Estimativa Numérica (NRS, Numeric Rating Scale) imediatamente, 7 dias e 3 meses depois. **Resultados:** O escore médio de dor nas costas da NRS no grupo HDL foi reduzida de 5 (intervalo: 4-8) para 4 (intervalo: 2-7) imediatamente após a injeção, para 2 (intervalo: 1-7) após 7 dias e para 2 (intervalo: 1-7) após 3 meses (valor de $p < 0,001$). O escore médio de dor nas costas do NRS do grupo ECL foi reduzida de 5 (intervalo: 4-8) para 4 (intervalo: 2-7) imediatamente após a injeção, para 2 (intervalo: 1-7) após 7 dias e para 3 (intervalo: 1-7) após 3 meses (valor de $p < 0,001$). O escore médio de dor na perna da NRS do grupo HDL foi reduzida de 5 (intervalo: 4-9) para 3 (intervalo: 3-7) imediatamente após a injeção, para 1 (intervalo: 1-6) após 7 dias e para 2 (intervalo: 1-7) após 3 meses (valor de $p < 0,001$). O escore médio de dor na perna da NRS do grupo ECL foi reduzida de 5 (intervalo: 4-9) para 4 (intervalo: 3-7) imediatamente após a injeção, para 3 (intervalo: 1-7) após 7 dias e para 2 (intervalo 1-6) após 3 meses (valor de $p < 0,001$). **Conclusão:** A IEE causa melhora estatisticamente significativa das dores nas costas e nas pernas em pacientes com HDL e ECL. No entanto, a eficácia a curto e médio prazo da IEE na ECL foi menor do que a da HDL. **Nível de evidência IV; Estudo prospectivo baseado em hospital.**

Descritores: Dor nas Costas; Hérnia; Estenose Espinal.

RESUMEN

Objetivo: Estudiar el papel de la inyección epidural de esteroides (IEE) en pacientes con hernia de disco lumbar (HDL) y estenosis del canal lumbar (ECL). Las IEE se utilizan regularmente para respaldar el tratamiento no quirúrgico del dolor lumbar y nuestra impresión empírica es que una proporción considerable de pacientes informa alivio sustancial del dolor después de la IEE. **Métodos:** Se incluyeron mil pacientes consecutivos (645 pacientes con HDL y 355 pacientes con ECL) que necesitaron IEE de enero a agosto de 2018. A todos se

Study conducted at the Manipal Hospital, Spine care department, Bangalore, Karnataka, India.

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les administró la misma IEE preparada con triamcinolona (80 mg), bupivacaina (0,25% 4 ml) y solución salina normal (4 ml). Los pacientes fueron evaluados usando una Escala de Valoración Numérica (NRS, Numeric Rating Scale) inmediatamente, 7 días y de 3 meses después. Resultados: La puntuación media de dolor de espalda de la NRS del grupo HDL se redujo de 5 (rango: 4-8) a 4 (rango: 2-7) inmediatamente después de la inyección, a 2 (rango: 1-7) después de 7 días y a 2 (rango: 1-7) después de 3 meses (valor de $p < 0,001$). La puntuación media de dolor de espalda de la NRS del grupo ECL se redujo de 5 (rango: 4-8) a 4 (rango: 2-7) inmediatamente después de la inyección, a 2 (rango: 1-7) después de 7 días y a 3 (rango: 1-7) después de 3 meses (valor de $p < 0,001$). La puntuación media de dolor de pierna de la NRS del grupo HDL se redujo de 5 (rango: 4-9) a 3 (rango: 3-7) inmediatamente después de la inyección, a 1 (rango: 1-6) después de 7 días y a 2 (rango: 1-7) después de 3 meses (valor $p < 0,001$). La puntuación media de dolor de pierna de la NRS del grupo ECL se redujo de 5 (rango: 4-9) a 4 (rango: 3-7) inmediatamente después de la inyección, a 3 (rango: 1-7) después de 7 días y a 2 (rango 1-6) después de 3 meses (valor $p < 0,001$). Conclusión: IEE causa una mejoría estadísticamente significativa en el dolor de espalda y piernas en pacientes con HDL y ECL. Sin embargo, la eficacia a corto y medio plazo de la IEE en la ECL fue menor que la de HDL. **Nivel de evidencia IV; Estudio prospectivo basado en hospitales.**

Descriptores: Dolor de Espalda; Hernia; Estenosis Espinal.

INTRODUCTION

Low back pain (LBP) is one of the most frequent ailments for which patients seek medical attention. It is so common that around 80% of people will suffer from it at some point during their lifetime.¹ Radiculopathy is a common symptom that affects around 40% of people, occurring at any time, but clinically significant radiculopathy only affects 4 to 6% of people.²

Herniated disc is the most frequent cause of radiculopathy. Some people with symptoms suggestive of radiculopathy may not show any disc prolapse in an MRI or CT scan, while others without symptoms may present disc prolapse.³ This contradiction has led to speculation on alternative explanations, since prolapsed intervertebral disc alone is not sufficient to produce features of radiculopathy. One such speculation is that there may be some local chemical supplement causing damage to the nerve roots.³ As technology has advanced, knowledge of radiculopathy has improved, leading to the realization that its pathogenesis is concomitant with inflammation, immunity, and mechanical compression.⁴ Phospholipase A2 (PLA2), an essential element of the intervertebral disc, triggers the release of Arachidonic acid, which is a progenitor of Leukotrienes and Prostaglandins, leading to inflammation of the nerve roots.⁵ Steroids are needed to reduce the inflammatory response incited by chemical, immunologic and mechanical mediators.⁶⁻⁹ Steroids may be used in radiculopathy patients who do not respond to NSAIDs (non-steroidal anti-inflammatory drugs). Local distribution of steroids into the epidural space gives a concentrated dose that will cause a long-lasting effect. Therefore, in patients who do not respond to the conservative treatment and who are contraindicated for surgical treatment, epidural steroid injections (ESIs) can be given. ESIs have been used to treat radiculopathy since they first emerged, around sixty years ago. Numerous studies have been conducted on this subject, but its efficacy is still controversial. In our set up, ESIs are regularly used to support non-operative treatment for LBP and our anecdotal impression is that considerable patients report substantial pain relief after this method, which in turn, saves on healthcare costs. This study investigates the short- to medium-term aftereffects of ESIs in patients with herniated disc and lumbar canal stenosis (LCS).

METHODS

All consecutive patients who underwent ESI for LBP with or without leg symptoms from Jan 2018 to Aug 2018 were selected. The sampling procedure was based on comfort: patients between 20 and 80 years of age with function-limiting LBP, with or without radiculopathy of at least 6 weeks' duration that did not respond to rest, oral medications or physiotherapy, were added to the study. Those with evidence of recurrent herniation, cauda equina syndrome, repeat injections, fractured vertebrae, and uncontrolled psychiatric disorders, as well as postoperative patients, were excluded.

All subjects were examined, and routine blood investigations, chest X-rays, and ECG were carried out. The severity of LBP and leg pain was assessed using the NRS. Written informed consent

was obtained from all the subjects included in this study. Patients' age, sex, marital status, smoking history, time of first episode, and number of episodes of LBP were recorded.

All injections were carried out as an outpatient procedure. The patient's vital signs were monitored.

After the necessary skin preparation, local anesthesia was given, with 5 ml of 2% xylocaine. The epidural space was identified i.e., one level above the affected level, using the prescribed landmark and the loss of resistance technique aided by an 18G Tuohy needle. Next, a premixed solution of 2 ml of 80 mg of Triamcinolone, 0.5 ml of 25 mcg of fentanyl, and 2 ml of local anesthetic (bupivacaine 0.25%), along with 6 ml of normal saline, was injected into the identified space, and the patient was asked to lie down in the supine position for 10 minutes. Immediately after the procedure (after 15 to 30 mins), the NRS was recorded. The patient was observed for one hour before being discharged.

The subjects were contacted over the phone and were interviewed to determine the NRS scores at regular intervals: 1 week and 12 weeks after the injection.

The outcome variables considered were a reduction in pain of more than 50%, at 15-30 min (immediate effect), 1 week (short-term effect); and 12 weeks (medium-term effect) after injection.

Descriptive statistical analysis was performed for age, sex, severity of LBP, and leg pain. Categorical data were analyzed using frequency and percentages.

RESULTS

ESI was administered to 1000 consecutive patients (645 patients with herniated disc, of which 388 (60.2%) were men and 257 (39.8%) were women and 355 patients with LCS, of which 216 (60.8%) were men and 139 (39.2%) were women) from Jan to Aug 2018. The age range of the study population was 20-80 years (the average age was 41.2 ± 11.5 years for herniated disc and 42.9 ± 13.1 years for LCS). All patients were given the same epidural injection prepared with triamcinolone (80 mg), local anesthetic bupivacaine (0.25%, 4 ml), and normal saline (4 ml). Patients were evaluated using functional outcome measures (numerical rating scale) immediately, 7 days, and 12 weeks after the injection. No complications were noted, except for temporary paresthesia post-injection in one patient.

The mean NRS back pain score of the herniated disc group was reduced from a pre-ESI score of 5 (range 4-8) to 4 (range 2-7) immediately after injection, 2 (range 1-7) after 7 days, and 2 (range 1-7) after 12 weeks (p -value of <0.001). The mean NRS back pain score of the LCS group was reduced from a pre-ESI score of 5 (range 4-8) to 4 (range 2-7) immediately after injection, 2 (range 1-7) after 7 days, and 3 (range 1-7) after 12 weeks (p -value of <0.001).

The mean NRS leg pain score of the herniated disc group was reduced from a pre-ESI score of 5 (range 4-9) to 3 (range 3-7) immediately after injection, 1 (range 1-6) after 7 days, and 2 (range 1-7) after 12 weeks (p -value of <0.001). The mean NRS leg pain score of the LCS group was reduced from a pre-ESI score of 5 (range 4-9) to 4 (range 3-7) immediately after injection, 3 (range 1-7) after 7 days, and 2 (range 1-6) after 12 weeks (p -value of <0.001).

Of the 645 herniated disc patients, surgery was needed in 59 (9.14%) patients, as their symptoms did not improve after the injection (15 patients at 1 month, 16 patients at 12 weeks, 10 patients at 4 months and 18 patients at 5 months after the injection). In 209 herniated disc patients (35.7%), the injection was ineffective at the end of 12 weeks. Of these, 31 underwent surgery and 178 continued to be managed conservatively. Nevertheless, 377 (64.34%) patients had a satisfactory outcome.

Of the 355 LCS patients, surgery was needed in 95 (16.7%), as their symptoms did not improve after injection (24 patients at 1 month, 26 patients at 12 weeks, 30 patients at 4 months, and 15 patients at 5 months after the injection). In 161 LCS patients, the NRS score was more than 40% at the end of 12 weeks i.e., 61.9% of the patients had an unsatisfactory outcome.

DISCUSSION

LBP and radiculopathy create a huge global burden. Its impact is significant at a global level, particularly in developing countries.¹⁰ Falling between conservative and surgical management of radiculopathy, ESIs are considered to be an intermediate treatment modality.^{11,12}

In 1952, Robecchi and Capra used hydrocortisone as the first ESI. Today, this has been replaced by different drugs, such as triamcinolone, methylprednisolone, dexamethasone, and betamethasone.¹³

Breivik and colleagues conducted a randomized controlled trial (RCT) in 35 patients with LBP and sciatica that did not respond to conservative management, and found that 65% of patients had good outcomes with ESI (methylprednisolone), returning to work as early as possible.¹⁴ Similarly, a study by Ridley et al. using methylprednisolone found 65% statistically significant improvement following ESI.¹⁵ Buttermann et al., in their study, found that 56% of patients who received ESI had good or favorable outcomes. But they also concluded that discectomy was more effective than ESI in relieving the symptoms in cases of large, herniated discs.⁹ An RCT by Valat, Rozenberg, et al. concluded that the ESI provided no additional benefit over isotonic saline; yet even in that study, 51% of patients had significant relief with ESI.¹⁶

This is a prospective cohort study involving 1000 patients who received ESI in the study period of January 2018 to August 2018. Of the total, 645 patients had herniated disc and 355 patients had LCS. Of the 645 patients who had herniated disc, 64.34% had good functional outcomes at the end of 12 weeks, which is consistent with the literature.

In relation to studies involving LCS, Kuan Liu et al. performed a meta-analysis, showing that ESI did not give a significant improvement in symptoms. In the LCS group of our study population, 161 out of 355 patients (61.9%) had poor functional outcomes at 12 weeks post-injection. Hence, it was found that the ESI was more effective in herniated disc than in LCS.

Buttermann's and Riew's studies involving disc herniation showed the crossover rate from ESI to discectomy to be around 50%.^{9,17} This high rate may be because of the higher number of large disc herniations in their study. Nevertheless, in a meta-analysis conducted by Lavalle et al., involving a large population (482,893) diagnosed with a disc herniation, 41,420 patients received ESIs and only 9.34% crossed over to the discectomy group.¹⁸ Similarly, our study showed that 35.66% of patients had NRS scores of more than 40%, and of these, 9.14% underwent surgery due to persistent symptoms.

The time interval for crossover from ESI to discectomy in the study by Buttermann et al. was 3.12 weeks [range: 1 to 13 months].⁹ Our study population showed an average crossover interval of 3.25 months. In the herniated disc group, 15 patients underwent surgery at 1 month, 16 patients at 12 weeks, 10 patients at 4 months, and 18 patients at 5 months. In LCS group, 24 patients underwent surgery at 1 month, 26 patients at 12 weeks, 30 patients at 4 months, and 15 patients at 5 months.

Nonetheless, our study has some limitations: the fact that it was not a randomized controlled study, and its short follow up time. Hence, an RCT with a longer follow up may result in a better assessment.

CONCLUSIONS

ESI gives a statistically significant improvement in back and leg pain in patients with herniated disc and LSC. However, the short- and medium-term efficacy of ESI in the LCS group was lower than in the herniated disc group.

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