Outcome Tools After Fluoroscopically Guided, Contrast enhanced, Lumbosacral Interlaminar Epidural Steroid Injections (IL ESI) – A Pilot Study.

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Research Design: Prospective, non-randomized, observational human study.

Purpose: To assess functional outcomes after fluoroscopically guided interlaminar epidural steroid injections

Background: Lumbosacral interlaminar steroid injections are an accepted treatment in the comprehensive, conservative care for low back pain with a radicular component secondary to lumbar disc pathology or spinal stenosis.6,8,9. There are papers both supporting and refuting the efficacy of IL-ESIs.1,2 However, these were performed without fluoroscopic guidance and have limited outcomes investigated. Instead, this study will be done with fluoroscopic guidance (contrast enhanced) and will utilize a full battery of functional outcome studies. This is a pilot study funded by the International Spinal Intervention Society (ISIS).

Inclusion/Exclusion Criteria: Patients who are undergoing lumbar interlaminar epidural steroid injections at our outpatient intervention spine practice will be enrolled in the study. Inclusion criteria are those we already use in our clinic for ESIs. These include patients with lumbar radicular pain (1. Shooting or lancinating pain radiating into the lower limb; 2. precipitated or aggravated by tension tests, such as straight leg raise or femoral stretch test; 3. Pain in the lower limb worse than pain in the back) and/or disc herniation (evidence on MRI of a disc herniation that compromises an adjacent spinal nerve or its root). Exclusion criteria include:

1. Any irreversible psychological barriers to recovery (e.g. drug addiction, or depression not due to persistent back pain)
2. Any anatomical anomalies that might interfere with the safe conduct of the procedure.
3. Any illness or disorder that interferes with the safe conduct of the procedure. These might include: allergy to local anesthetics, antibiotics, or radiographic dyes; a tendency to bleed; or an inability to lie still, e.g. because of persistent cough;
4. Pregnancy;
5. Inability to provide the information necessary to assess the outcome of the treatment.
6. Concomitant, painful conditions, such as hip pain, that might interfere with the patient’s ability to determine the degree of relief of their radicular pain.
7. Conditions, such as spinal stenosis or spondylolisthesis of grade greater than 2, which might constitute alternative causes of radicular and which are not known to be responsive to treatment with ESIs.
8. Previous treatment with ESIs at inception.
9. Litigation
10. Worker’s compensation
11. Age younger than 18 years old.
12. Self-reported 3 day average pain score less than 5/10 at inception.
13. Previous surgery in the lumbar spine.
14. Radicular lower limb pain that is less painful than axial low back pain at inception.

Additionally, patients will be dropped from the study after being enrolled if an exclusion criteria condition occurs during the course of their participation in the study or they elect to have surgery or a different type of injection (transforaminal epidural steroid injection, medial branch blocks, etc.) They will also be dropped from further participation in the study if they have a major surgery, suffer a major trauma (such as sustained in a motor vehicle accident), or are diagnosed with a new major medical condition (such as metastatic cancer) during the course of their participation in the study that would possibly cause new radicular or non-radicular pain.
Patient Enrollment:
Those meeting the above inclusion and exclusion criteria will be presented the option of participation. The participants, then will be presented the research consent form in addition to our standard consent form (attachment 1). The interventionist (MBF, JLG, DMG, MAK) will determine the appropriate level to inject according to the patient’s clinical scenario radiographic imaging studies using our typical technique for IL-ESI. Estimated number of patients to be enrolled is 50. Patients will be paid $25 to compensate for transportation and time to fill out the paper work for the initial baseline data and each subsequent study-related follow-up visit.

Repeat Treatment:
If an enrolled patient experiences satisfying relief from their initial treatment, but that relief wanes, the patient may elect to have that treatment repeated within a 12 month period following the initial treatment or follow-up injection. If a patient elects to have their treatment repeated, they will resume assessment as if the repeat treatment constituted their first treatment. However, they will be recorded as having a repeat treatment, and records will be maintained of each period of response after each treatment. Up to a total of three treatments (inception treatment and two follow-up treatments) will be allowed. If, after 3 treatments, the patient’s response wanes, they may elect to pursue an escape treatment (surgical consultation or a different type of injection).

Research Procedures:
All procedures will be performed in our procedure suite under fluoroscopic guidance with contrast enhancement by one of the attendings in the practice (MBF, JLG, DMG, MAK). The patients will be prepped and draped in a sterile fashion in the prone position for the procedure. A registered nurse will occasionally obtain intravenous access, provide optional sedation and monitor appropriate vital signs and pulse oximetry as per our usual protocol.

For these lumbar interlaminar epidural steroid injections, we will use our standard protocol, as follows: The fluoroscope will be positioned so that an anteroposterior (AP) view of the appropriate interlaminar space is visualized. The overlying soft tissue will be then anesthetized with 1% Lidocaine without epinephrine. An appropriate length epidural needle will be inserted into the epidural space using the paramedian approach. Under biplanar visualization, the needle will be advanced into the epidural space. Epidural placement will be confirmed with “loss of resistance” and contrast injection confirmed in two planes.

Initially 1cc of 2% Lidocaine without epinephrine will be injected as a test dose and after 60 seconds, if there is no weakness or numbness in the lower limbs, the remainder of the solution containing 2cc of Triamcinolone (40mg/ml) and 2cc of normal saline will be injected into the epidural space.

The research technique described above is our typical treatment technique.

Data to be collected include the following outcome measures, which will be collected pre-procedure and post-procedure at 2 weeks, 6 weeks, 3 months, 6 months, 9 months, and 12 months:

Numeric Pain Rating Scale (NPRS)
SF-36 Health Survey
Roland-Morris Disability Questionnaire
Assessment of Quality of Life Instrument (AQOL)
Work history
Analgesic use log

Ancillary treatment log

Reports of overall degree of pain relief or lack thereof on an 8-point LIKERT scale

How many of their four specific ADLs are partially or completely restored.

They will be asked if they would repeat the treatment for the results obtained.

Other data collected at inception, include the following epidemiologic data:
   Gender, age, date of birth, diagnosis (backache with radiation in lower extremities and level of lumbar disc
   injury), level of injection, use of prescription pain medications and medical aid, level of assistance needed
   in daily life, social relationships, physical senses, communication with others, psychological well being,
   duration of symptoms, occupational status.

Data analysis will be conducted

Risks/Benefits:
   **Risks:** Infection, allergic reaction to medications, nerve damage, paralysis, epidural hematoma,
   headache, syncope, scar, increased pain 1-3 days after the procedure, respiratory/cardiac arrest and if
   diabetic, possibly increased blood sugar level(s). These are the normal risks associated with lumbar
   epidural steroid injections. **There are no increased risks by participating in the research protocol.**

   **Benefits:** Resolution of pain symptomatology and increased function.

Should the results of this pilot study show reasonable functional benefits, it will be repeated in a more rigorous
manner (i.e. double blind rCT).

**Intended Use of the Results:**
Depending on our findings, we may recommend this treatment to improve quality of life outcome for people
suffering from backache with radicular symptoms radiating to lower extremities.

**References:**

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