A prospective study of role of epidural steroid injection in intervertebral disc prolapse in adults

B Sahithya and Gopal Arunkumar

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Abstract
Back pain is a major issue in our country and its effective management remains a challenge. Prolapsed intervertebral disc is one of the major cause of illness leading to low back ache which is mostly affecting adults in their fourth decade of life. We have selected a study group of 120 people with single and double level disc bulges and prolapses, who underwent MRI for their low backache and managed them with ESI by different approaches, among which 63 patients were given interlaminar approach, 21 transforaminal approach and 36 caudal approach at the end we got fair to good results in our study, by this the time interval for surgical intervention has been increased.

Keywords: low back pain, intervertebral disc prolapse, epidural steroid injection

Introduction
Back pain is now an international health issue of major significance, Disc prolapse amounts for 5% low back disorders & is one of the most common cause for surgery. Degenerative disc disease is an important cause of low back pain, which is commonly sen in lumbar discs, L3-L4 and L4-L5 intervertebral disc levels showed the greatest area of disc degeneration [1, 2]. Treatment for lumbar disc herniation can be conservative or surgical & which one is effective is always controversial [3]. Epidural steroid injection is very popular & low risk alternative to surgical intervention in lumbar disc herniation [4]. ESI enjoys reasonable success rates for alleviation of radicular symptoms from lumbar herniation discs. Different approaches of epidural steroid injection has different outcome on patients treated for low backache. Even though all 3 modalities deliver medication into the epidural space, there are important differences among these approaches [5-9]. So, for this we have conducted a prospective study on patients with disc prolapse at lumbar level and tried different approaches of epidural steroid injection, which has shown a statistically significant results.

Aims and Objectives
a. To study the efficacy of epidural steroid injection in alleviating symptoms caused by prolapsed intervertebral disc.
b. To compare the outcome with different approaches of epidural steroid injection.
c. To study the risks following epidural steroid injection.

Material and Methods
This interventional study was conducted in the Orthopaedic department of Mamata general and super speciality hospital, Khammam.
The case selection criteria includes

Corresponding Author:
Gopal Arunkumar
Senior Resident (M.S. Orthopaedics), Mamata General and Super Speciality Hospital, Khammam, Telangana, India

Inclusion Criteria
1. Back pain for more than 6weeks in an adult with evidence of lumbar disc herniation on MRI, with failed conservative management (tractions, analgesics, physiotherapy).
2. Disc herniation with radiculopathy.
Exclusion Criteria
1. Back pain less than 6 weeks.
2. Patient with focal neurological deficit’s.
3. Patient with multiple level intervertebral disc involvement.
4. Those without evidence of lumbar disc herniation on MRI.
5. Osseous cause for lumbar canal stenosis on MRI.
6. Signs of lumbar disc degeneration without lumbar disc herniation on MRI.
7. Presence of other associated spinal pathologies.
8. Those with “cauda equina syndrome”.
9. Those with prior spine surgery.

The period for inclusion of patients was from March 2019 to March 2021 and all the patients were followed up for a minimum period of 1½ year.

Procedure
Technique of epidural injection It is an aseptic procedure done in the operation theatre under the guidance of an Anaesthetist to face any complications associated with ESI. An IV cannula should be placed in situ for at least 4 hrs to be able to tackle any hypotension that ensures. There are three common methods for delivering steroid into the epidural space:

**Interlaminar injection**: the needle is inserted into the space between adjacent vertebral laminae (posterior wall of the vertebra) to reach the epidural space.

**Transforaminal injection**: the needle is inserted into the epidural space through the intervertebral foramen on the side of the spinal canal.

**Caudal injection**: the needle is placed into the sacral area below the lumbar spine through an opening called the sacral hiatus.

Before the injection is given the procedure is carefully explained to the patient, who is told to expect increase in intensity of his symptoms during the injection.
Fig 4: a) Caudal ESI, b) Interlaminar ESI, c) Transforaminal ESI

Fig 5: Confiming the correct placement of needle in epidural space by doing lose of resistance and hanging drop technique

Fig 6: Injection of epidural steroid by 3 different approaches

Post procedure advice
Post procedure patient is advised bed rest, avoid straining / bending. Patient is advised to sleep in propped up position, plenty of oral fluids.

Number and Frequency of ESI
If the first injection fails to relieve symptoms, further injections can be given at 2-week intervals. The number of injections is a matter of personal choice, but a total of three injections would appear to be a reasonable limit.

Observation and Results
A total of 148 patients with low back ache are taken in this study, out of which only 120 patients attended the study, so 28 patients were excluded from this study. All the patients presented in the outpatient department with pain in the lower back radiating to one or both the lower limbs with paresthesia and difficulty in performing daily activities. These patients had a failed trial of conservative line of management like medications, pelvic traction, physiotherapy and other treatment modalities for more than 6 weeks. These patients were analysed clinically and radiologically by taking an x-ray, firstly by taking an MRI for all those who fulfilled our inclusion and exclusion criteria were planned for epidural steroid injection. All the patients were evaluated before and after the ESI using VAS, ODI and SF36, later the patients
were followed at 1 month, 2 months, 3 months, 6 months, 1 year and 1½ year after injection. The mean age was 47.7 with maximum patients lying in the age group between 41-50 years. 80 out of 120 patients were females and 40 out of 120 were males. (Table 1)

| Age   | Male | Female | Total |
|-------|------|--------|-------|
| 20-30 | 4    | 6      | 10    |
| 31-40 | 7    | 13     | 20    |
| 41-50 | 18   | 30     | 48    |
| 51-60 | 6    | 16     | 22    |
| 61-70 | 8    | 12     | 20    |

We have selected patients with single level disc bulge on MRI, and based on the type and level of disc bulge we opted for best approach. (Table 2 & 3)

| Type of discs | No. of patients | Percentage |
|---------------|-----------------|------------|
| Disc bulge    | 68              | 56.6%      |
| Protrusion    | 32              | 26.6%      |
| Extrusion     | 20              | 16.6%      |
| Sequestration | 0               | 0%         |
| Total         |                 |            |

| Types of approaches | No. of patients | Percentage |
|---------------------|-----------------|------------|
| Interlaminar        | 63              | 52.5%      |
| Transforaminal      | 21              | 17.5%      |
| Caudal              | 36              | 30%        |
| Total               | 120             |            |

Once collected, the data was exported to Statistical Analyzing System (SAS Institute Inc., Cary, N.C.) for statistical analysis. Repeated ANOVA was used to study the effectiveness of treatment, and independent sample mean comparisons to compare treatments. The following are the results obtained in the study. Base line characteristics (N=120)

| VAS | ODI | SLRT |
|-----|-----|------|
| Before ESI | N | Mean | SD | P. value | N | Mean | SD | P. value | N | Mean | SD | P. value |
| IL | 63 | 5.524 | 1.554 | 0.909 | 63 | 32.762 | 5.389 | 0.155 | 63 | 31.603 | 3.549 | 0.617 |
| TF | 21 | 5.429 | 1.690 | 21 | 31.286 | 4.173 | 21 | 31.667 | 2.817 | 21 | 31.222 | 2.231 | 21 | 31.143 | 3.535 | 0.714 |
| C | 36 | 5.611 | 1.420 | 36 | 34.333 | 6.520 | 36 | 34.333 | 6.520 | 36 | 34.333 | 6.520 | 36 | 31.111 | 3.319 | 0.714 |
| At 1mth | N | Mean | SD | P. value | N | Mean | SD | P. value | N | Mean | SD | P. value |
| IL | 63 | 3.492 | 0.878 | 0.001 | 63 | 23.603 | 5.738 | 0.015 | 63 | 23.603 | 5.738 | 0.015 | 63 | 23.603 | 5.738 | 0.015 |
| TF | 21 | 4.000 | 0.000 | 21 | 24.952 | 4.466 | 21 | 24.952 | 4.466 | 21 | 24.952 | 4.466 | 21 | 24.952 | 4.466 | 21 | 24.952 | 4.466 | 0.002 |
| C | 36 | 3.944 | 0.333 | 36 | 26.889 | 5.115 | 36 | 26.889 | 5.115 | 36 | 26.889 | 5.115 | 36 | 26.889 | 5.115 | 36 | 26.889 | 5.115 | 0.028 |
| At 6mths | N | Mean | SD | P. value | N | Mean | SD | P. value | N | Mean | SD | P. value |
| IL | 63 | 4.032 | 0.439 | 0.375 | 63 | 25.508 | 4.310 | 0.228 | 63 | 25.508 | 4.310 | 0.228 | 63 | 25.508 | 4.310 | 0.228 |
| TF | 21 | 4.095 | 0.436 | 21 | 24.952 | 4.466 | 21 | 24.952 | 4.466 | 21 | 24.952 | 4.466 | 21 | 24.952 | 4.466 | 21 | 24.952 | 4.466 | 0.714 |
| C | 36 | 3.944 | 0.333 | 36 | 26.889 | 5.115 | 36 | 26.889 | 5.115 | 36 | 26.889 | 5.115 | 36 | 26.889 | 5.115 | 36 | 26.889 | 5.115 | 0.714 |
| At 1yr | N | Mean | SD | P. value | N | Mean | SD | P. value | N | Mean | SD | P. value |
| IL | 63 | 4.095 | 0.560 | 0.086 | 63 | 31.603 | 3.549 | 0.617 | 63 | 31.603 | 3.549 | 0.617 | 63 | 31.603 | 3.549 | 0.617 |
| TF | 21 | 4.476 | 0.873 | 21 | 31.667 | 2.817 | 21 | 31.667 | 2.817 | 21 | 31.667 | 2.817 | 21 | 31.667 | 2.817 | 21 | 31.667 | 2.817 | 0.714 |
| C | 36 | 4.167 | 0.737 | 36 | 32.222 | 2.231 | 36 | 32.222 | 2.231 | 36 | 32.222 | 2.231 | 36 | 32.222 | 2.231 | 36 | 32.222 | 2.231 | 0.714 |

SF36:
The patients were followed at 1st month, 2nd month, 3rd month, 6th month, 1 year and 1½ years and mean and standard deviation were calculated.

| Role limitations due to emotional problems | N | Mean | Std. deviation | P-value |
|------------------------------------------|---|------|----------------|--------|
| Interlaminar | 63 | 65.778 | 28.476 | 0.031 |
| Transforaminal | 21 | 47.335 | 34.236 | 0.001 |
| Caudal | 36 | 66.306 | 26.561 | 0.001 |

| Pain | Interlaminar | 63 | 58.024 | 9.927 | 0.011 |
| Transforaminal | 21 | 51.238 | 12.881 | 0.011 |
The following results were analysed and they have proven to be highly significant statistically at 2nd, 3rd and 6th month, After 3 months, there was no significant differences between the groups, and among the approaches interlaminar was superior to transforaminal which is again superior to caudal approach. Epidural steroid injection is definitely showing good and short term improvement in patients with intervertebral disc herniations.

**Cases**

**Case 1**

| Complications                      | No. of Patients |
|------------------------------------|-----------------|
| Injection site pain                | 7               |
| Transient head ache                | 5               |
| Steroidal side effects (hypotension)| 2               |
| Dural puncture                     | 2               |
| PDPH (post dural puncture headache)| -               |
| Nerve injury                       | 3               |
| Others                             | -               |

In our study among 120 patients, 15 of them had immediate hypotension following ESI, 18 patients had nerve injury, 5 patients faced dural puncture with CSF leakage, and the rest 5 had post dural puncture headache there were no risks like infection, HPA axis suppression and spinal arachnoiditis following ESI.

|                | (I) type of esi | (J) type of esi | Mean Difference (I-J) | P-value |
|----------------|-----------------|-----------------|----------------------|---------|
| Role limitations due to emotional problems | Interlaminar | Transforaminal | 18.444 | 0.013 |
| Caudal         |                 |                 | -0.528               | 0.931   |
| Transforaminal | Interlaminar    | -18.444         | 0.013                |
| Caudal         | Interlaminar    | -18.972         | 0.019                |
| Pain           | Interlaminar    | Transforaminal | 6.786                | 0.015   |
| Caudal         |                 |                 | 5.579                | 0.016   |
| Transforaminal | Interlaminar    | -6.786          | 0.015                |
| Caudal         | Interlaminar    | -1.206          | 0.688                |
| Transforaminal | Interlaminar    | -5.579          | 0.016                |
| Caudal         | Interlaminar    | 1.206           | 0.688                |
| Transforaminal | Interlaminar    | 5.079           | 0.006                |
| Caudal         | Interlaminar    | 0.238           | 0.876                |
| Transforaminal | Interlaminar    | 5.317           | 0.009                |

**Table 5**: Distribution of study subjects according to different complication following ESI

| Complications                      | No. of Patients |
|------------------------------------|-----------------|
| Injection site pain                | 7               |
| Transient head ache                | 5               |
| Steroidal side effects (hypotension)| 2               |
| Dural puncture                     | 2               |
| PDPH (post dural puncture headache)| -               |
| Nerve injury                       | 3               |
| Others                             | -               |

MRI Findings: Interlaminar Approach

~ 250 ~
Outcome measures

|                | VAS score | ODI | SLRT |
|----------------|-----------|-----|------|
| Pre-ESI        | 8         | 31  | 2    |
| 1mth of ESI    | 4         | 26  | 4    |
| 1½year ESI     | 4         | 17  | 3    |

There is significant improvement in the scores before and after ESI.

Case 2

|                | Name       | Age/Sex   | Diagnosis | Type of approach |
|----------------|------------|-----------|-----------|------------------|
|                | B. krishna | 63yr/M    | L4-L5     | Transforaminal   |

Case 3

|                | Name       | Age/Sex   | Diagnosis | Type of approach |
|----------------|------------|-----------|-----------|------------------|
|                | Vishwanath | 26y/m     | IVDP L5-S1| Caudal           |

There is significant improvement in the scores before and after ESI.

**Discussion**

Epidural steroid injections are commonly used to relieve pain and radicular symptoms caused by lumbar disc herniations, and have shown good short term improvement with out surgery [10-13]. Its use in chronic degenerative disc disease with canal stenosis due to other causes is still debatable [14]. Medicare data files shows that the number of ESI performed in the united states increased from 444,000 in 1993 to 636,000 in 1998 but dropped to 482,000 in 1999. [13] Anesthesia
providers performed at least 75% of these procedures every year and 85% in 1999. While interlaminar and caudal approach [15] is the traditionally used approach, recently there is interest in transforaminal approach [16, 17] and this approach has shown slight advantage over interlaminar approach but technically more demanding. This approach needs image guidance. According to reports, epidurals from the 1920s-1940s involved using high volumes of normal saline and local anesthetics. Injection of corticosteroids into the epidural space for the management of lumbar radicular pain was first recorded in 1952. Epidural steroid injection is one of the therapeutic interventional therapy. There are a multitude of interventional techniques in the management of chronic pain, including not only neural blockade but also minimally invasive surgical procedures such as peripheral nerve blocks, trigger-point injections, facet joint injections, sympathetic blocks, neuroablation techniques, intradiscal thermal therapy, disc decompression, morphine pump implantation, and spinal cord stimulation.

In our study we have laid emphasis on treating radiculopathy and pain caused by intravertebral disc prolapse with epidural steroid injection by 3 different approaches based on the type of disc prolapses, this is the simple and relatively effective method in improving the symptoms of the patients. It is one of the best treatment modalities in order to postpone the early surgical treatment. We have conducted our study on 120 patients. In our study the mean age of the patient was 47.7 with the maximum patients between 41-50 years, according to the literature intervertebral disc prolapse occurs above >35 years of age. Age appears to be one of the important factors in the aetiology of this condition, among 120 patients there were 40 male and 80 female patients, out of 120 patients 63(52.5%) patients were tried with interlaminar approach, 21 out of 120 patients were tried with transforaminal approach and 36 out of 120 patients were tried with caudal approach. All patients were clinically evaluated for improvement in pain, disability status, quality of life and functional status. Outcome was assessed using Visual analogue score on a scale of 0 to 10 for pain, Oswestry disability index [17, 18] for function, slr for functional outcome and sf36 for assessing the quality of life. Outcome was measured at consecutive months and lastly 1yr, 1. 5yrs. Two way Anova test was used to analyse these results as the data is normally distributed.

TheVAS score has ranged between 2 to 8 per patient with the mean for IL, TF and C as 5.53±1.55, 5.429±1.69 and 5.611±1.420. The patients were followed after 1month, 2months, 3months, 6months, 1 year and 1½ year respectively, when statistical analysis was done comparing the mean VAS scores before and after injection for different approaches the results obtained were highly significant at \( p < 0.01 \) 2nd, 3rd and 4th follow up’s. The ODI for LBA patients ranged between 13% to 42% per patient with a mean ODI for different approaches IL, TF and C is 32.762±5.8, 31.28±4.1 and 34.33±6.2 respectively. The patients were followed after 1month, 2months, 3months, 6months, 1 year and 1½ year respectively. Among the 8 components of SF36, in our study 3 components were selected to access the quality of life of the patients. When statistical analysis was done comparing the mean VAS, ODI, SLRT and SF36 scores before and after injection for different approaches the results obtained were highly significant at \( p < 0.01 \) 2nd, 3rd and 4th follow up’s. When statistical analysis was done by multiple comparisons in between 3 approaches, at 2nd, 3rd, 4th follow up’s has shown interlaminar approach to be superior when compared to transforaminal and caudal approach, in between TF and C, TF was superior at 2nd, 3rd and 4th follow up’s. In our study among 120 patients 5 of them had injection site pain, 6 out of 120 had transient head ache and 2 out of 120 developed hypotension. By careful evaluation of the effects of these injections the drawbacks and advantages of this procedure could be concluded.

Conclusion
Epidural steroid injection will serve an important role in alleviating the symptoms caused by herniated disc. The ESI offered a more simple and easy method of treatment, it definitely is more appealing due to less deleterious effects and being a minimally invasive procedure.
Epidural steroid is a good low cost alternative to fenestration discectomy for temporary relief of symptoms of lumbar disc herniation especially radiculopathy.
ESI therapies have many different compositions and approaches for application, they all try to alleviate the symptoms caused by herniated disc.
Among the 3 different approaches in our study interlaminar approach gave superior results when compared to transforaminal and caudal.
The vast majority of complications related to ESI are minor.
Common complications include injection site pain or soreness, infections, allergy, and inadvertent dural puncture with spinal headache.
SF 36 is a useful questionnaire to evaluate quality of life in an Indian setting though some aspects of it are not applicable to the rural population especially pertaining to physical functioning.

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