Therapeutic efficacy of selective nerve root blocks in the management of lumbar radicular pain

Dr. Mihirkumar Patel, Dr. F Abdul Khader and Dr. Adhiyamaan RV

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Abstract
Lower back pain is generally most common musculoskeletal complaint in routine clinical practice now a days. Lower back pain is most significant reason behind development of walking disability. Irritation and pressure on nerve root in lumbar region leads to Lumbar sacral radiculopathy and its very painful condition. Reason behind radiculopathy can be herniating disc in lumbar region, vertebral defect or disintegration and neural foramen size decrease. Epidural steroid injection is effective treatment for lumbar pain. Study objective is to assess the efficacy of hypertonic saline in radicular lower back pain. Numerical Rating Scale (NRS) and Oswestry Disability Index (ODI) was used as data collecting tools. comparison between intervention and control group for pain score at three and six months. With p value =0.04 and 0.02 respectively for 3 and 6 months. As conclusion was Superior and longer duration of effect was observed with addition of hypertonic saline along with steroid in lumbar radiculopathy. And this can be used as a major cost-effective adjuvant.

Keywords: Lower back pain, lumbar radiculopathy, selective nerve root block, hyper tonic saline

1. Introduction
Pain in lower back is one of the most common problem that people feel in their life in various point. Lower back pain is generally most common musculoskeletal complain in routine clinical practice now a days. Lower back pain is most significant reason behind development of walking disability. Various epidemiological studies shows the incidence of first episode of lumbar back pain is between 5 to 10 percent. Majority cases of lower back pain are self-limiting conditions [1]. Irritation and pressure on nerve root in lumbar region leads to Lumbar sacral radiculopathy and it’s very painful condition. Reason behind radiculopathy can be herniating disc in lumbar region, vertebral defect or disintegration and neural foramen size decrease. Lumbar radiculopathy can be manifested by pain radiating to lower limb in specific pattern of skin dermatome, degree of sensation loss, any reflex abnormality like loss [2]. The pathophysiology of radiculopathy is physically or chemically mediated, other reasons are ischemic condition because of decreased blood flow or reduced nutrients supply [3]. MRI is most valuable diagnostic method for lumbar radicular pain. According to severity of pain and disability various conservative treatment are used like… steroids, NSAIDs, Tricyclic anti-Depressants (TCAs), muscle relaxation techniques, physiotherapy, chirotherapy, traction and steroid injections. among this techniques Epidural steroid injection is most effective treatment for lumbar pain. Epidural steroid injection reduces inflammatory changes and also reduce blood flow. (4)(5). Study objective was to assess the efficacy of hypertonic saline in radicular lower back pain.

2. Methodology
Ethical committee permission was obtained from Shri Sathya Sai Medical College & Research Institute, a tertiary care hospital, Ammapettai. It was a double blinded randomized control study with Study population was patients who were referred to orthopaedic department for radicular pain. Sample size was calculated according to Behnam Hosseini et al. study [6], mean and standard deviation was considered of pain score in intervention group as 4.43 ± 1.5, and in control

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group as $5.39 \pm 1.35$ at 95% confidence interval with 80% power, the sample size was calculated as

$$N = \left( r + 1/r \right) \times \left( \frac{Z_{1-\alpha/2}^2 + Z_{1-\beta}^2 \times \sigma^2}{(\mu_1 - \mu_2)^2} \right)$$

$Z_{1-\alpha/2}$ - two tailed probability for 95% confidence interval = 1.96, $Z_{1-\beta}$ - two tailed probability for 80% power = 0.84, $\mu_1$ - mean of pain score in intervention group = 4.43, $\mu_2$ - mean of Pain score in control group = 5.39, $\sigma$ - average standard deviation of pain score in intervention group & Pain score in control group = 1.43

$$N = \frac{1}{(1.96 + 0.84)^2} \times 1.42697231928303^2 / (4.43 - 5.39)^2$$

$N = 34.68$, Final sample size was 70 with 35 patients in each group.

Sampling method: Convenient sample size was used to recruit all the eligible subject till the required number of subjects were reached. Patients were randomly divided in A and B groups by randomized program generated by computer.

Group A (Intervention Group) patient were treated by 2ml bupivacaine 5% + 1ml betamethasone (40 mg) + 2ml 10% hypertonic saline. Group B (Control Group) patient were treated by 2 ml bupivacaine 5% + 1 ml betamethasone (40 mg). Follow up was taken at 3- and 6-months post procedure. With total study period was one and half year.

Inclusion criteria was age of patient more than 25 years, patients had taken pharmacology and physiotherapy but it was failed. Pain duration was more than 8 week and no surgical intervention done in past. Patients were excluded who had previously undergone spinal surgery, suffered from spinal fracture, cerebral vascular accidents, potts spine and associated with co-morbidity, pregnant women. Numerical Rating Scale (NRS) and Oswestry disability index was used as data collecting tools. Statistical analysis was done by mean and standard deviation for quantitative data and frequency and proportion for qualitative data. Shapiro wilk test and chi square test were used for establishing statistical correlation. All analysis was done in IBM SPSS version 20 Software

3. Results

<table>
<thead>
<tr>
<th>Variables</th>
<th>Control</th>
<th>Intervention</th>
<th>Table value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (SD)</td>
<td>46.43(9.32)</td>
<td>44.51(7.79)</td>
<td>1.46</td>
<td>0.23</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17(63%)</td>
<td>10(37%)</td>
<td>2.95</td>
<td>0.09</td>
</tr>
<tr>
<td>Female</td>
<td>18(41.9%)</td>
<td>25(58.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height in m</td>
<td>1.68(0.049)</td>
<td>1.67(0.050)</td>
<td>0.14</td>
<td>0.71</td>
</tr>
<tr>
<td>Weight in kg</td>
<td>65(6.97)</td>
<td>66.63(6.42)</td>
<td>0.26</td>
<td>0.61</td>
</tr>
<tr>
<td>BMI in kg/m²</td>
<td>23.12(2.40)</td>
<td>23.82(1.62)</td>
<td>0.07</td>
<td>0.79</td>
</tr>
<tr>
<td>NRS prior injection</td>
<td>5.57(0.66)</td>
<td>5.37(0.77)</td>
<td>0.36</td>
<td>0.55</td>
</tr>
<tr>
<td>ODI prior injection</td>
<td>50.94(5.88)</td>
<td>47.69(6.45)</td>
<td>0.75</td>
<td>0.39</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Variables</th>
<th>Control group</th>
<th>Intervention group</th>
<th>Table value</th>
<th>p value</th>
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</thead>
<tbody>
<tr>
<td>Three months</td>
<td>3.80(0.63)</td>
<td>3.51(0.61)</td>
<td>0.52</td>
<td>0.049</td>
</tr>
<tr>
<td>Six months</td>
<td>1.91(0.66)</td>
<td>1.57(0.56)</td>
<td>0.27</td>
<td>0.02</td>
</tr>
</tbody>
</table>

**Graph 1**: Comparison of NRS Score at 3 and 6 months

<table>
<thead>
<tr>
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<th>Control group</th>
<th>Intervention group</th>
<th>Table value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three months</td>
<td>34.11(4.42)</td>
<td>30.46(3.44)</td>
<td>0.82</td>
<td>0.03</td>
</tr>
<tr>
<td>Six months</td>
<td>21.71(3.04)</td>
<td>17.69(2.44)</td>
<td>0.69</td>
<td>0.01</td>
</tr>
</tbody>
</table>
4. Result and Discussion
Table 1 shows comparison of Socio-demographic profile between control and intervention groups. There is no significant difference between gender in both groups (p=0.09) where chi square test is used. There is no significant difference for Age, Height, Weight, BMI, NRS and ODI score as p value is >0.05 here t test is used for correlation. That suggest randomization was appropriate in present study.
Table 2 shows comparison between intervention and control group for pain score at three and six months. There is a significance difference between both the groups at three months as well as six months. With p value = 0.04 and 0.02 respectively for 3 and 6 months. Mean pain score in intervention group was 3.51 which was lesser then control group (3.80). At six months again mean score is lesser in intervention group in comparison of control group (1.57 and 1.91 respectively). same information is shown graphically in graph 1 which shows comparison at prior to injection at three months and six months through line chart.
Table 3 shows comparison between intervention and control group for ODI score at three and six months. There is a significance difference between both the groups at three months as well as six months. With p value = 0.04 and 0.02 respectively for 3 and 6 months. Mean ODI score in intervention group was 30.44 which was less than control group [10]. At six months again mean score is lesser in intervention group in comparison of control group (17.69 and 21.71 respectively). same information is shown graphically in graph 2 which shows comparison at prior to injection for ODI score at three months and six months through line chart.
Many studies have reported similar findings which showed pain and disability scores are reduced by addition of hypertonic saline [7-11]. The addition of hypertonic saline during percutaneous epidural adhesiolysis is consideration to add to the adhesiolysis of possible adhesions and fibrous tissues in the epidural and perineural space. Although mechanical adhesiolysis has been report to be a dangerous issue in adhesiolysis, the position of hyper tonic saline in breach fibrous adhesions is divisive [10, 12].
Another important factor is Chemical adhesiolysis, such as diminution in edema and inflammation. Human fibroblast cell proliferation has been found to have inhibitory effect from hypertonic saline. Hyper tonic saline have neuromodulator effect which can be another possible reason for present study results. neuromodulatory effects of chloride solutions and the effects of hyperosmolar solutions on nerve conduction has been established in a few experimental animal study. According to King al., When dorsal rootlets are exposed to hypertonic saline persistent c fibre blockade were done by chloride ions. Another reason is hyperosmolar solution effect on signal propagation and the compound action potential amplitude of A-fibres in the rat dorsal root ganglion, so it is assumed that the hyper osmolarity of the sodium chloride solution that was administered could have contributed to changes in pain conductivity [13-15].
Our study had some limitations. Scale use for assessing pain and disability have reduced uniformity and integrity of study so inability to generalize the result. Another not aware of other treatment taken for pain by subject while follow up period because of this pain and disability can increase or decrease. one more was hypertonic saline injection may lead to some side effect and complication which did not mention in our study.

5. Conclusion
Superior and longer duration of effect was observed with addition of hypertonic saline along with steroid in lumbar radiculopathy. And this can be used as a major cost-effective adjuvant.

6. References


