Original Article

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Orthopaedics Section

A Randomized Controlled Clinical Trial to Determine the Effectiveness of Caudal Epidural Steroid Injection in Lumbosacral Sciatica

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ABSTRACT

Introduction: Caudal epidural steroid injection have been a part of nonsurgical management of lumbosacral sciatica since last half a century but various randomized controlled trials fail to provide convincing evidence in favour of its effectiveness.

Aim: To assess the efficacy of caudal epidural steroid injection in patients of lumbosacral sciatica in comparison to placebo.

Materials and Methods: The study consisted of patients of sciatica caused by lumbosacral disc prolapse (observed on Magnetic Resonance Imaging (MRI) scan). Caudal epidural injections of 80 mg methyl prednisolone were injected in 47 patients in one group. The other group consisted of 46 patients who were injected isotonic saline as placebo. Self-evaluation was the main judgment criterion at 4th week using a descriptive four item scale (recovery, marked improvement, slight improvement, or worse). Patients rating the improvement as "recovery" or "marked improvement" were considered as success. Patients rating the improvement as "slight improvement" or "worse" were considered as failure. Only paracetamol were authorized and patients requiring Non Steroidal Anti-inflammatory Drugs (NSAIDs) before 4th week were also considered as failure.

Results: On analysis per protocol, at 4 weeks, the two groups differed significantly with respect to the primary outcome: among the 93 patients, 8/46 (17%) in the placebo group and 32/47 (68%) in the steroid group (p=0.000) were considered as success (difference 50.7%; 95% CI for the difference 33.4 to 67.99). But at the end of the study (week 12) there was no significant difference in primary outcome between the groups: 22/46 (48%) patients in the placebo group and 28/47 (60%) in the steroid group (p=0.25) were considered as success (difference 11.8%; 95% CI for the difference -8.38 to 31.9).

Conclusion: Caudal epidural steroid injections provide no additional improvement over placebo in the long term natural history of lumbosacral sciatica. However, it can be an important component of short term management of painful sciatica.

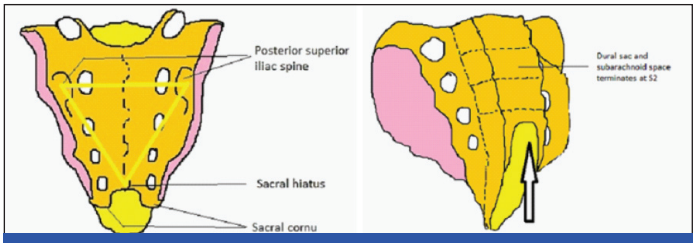
Keywords: Lumbar canal stenosis, Prolapsed intervertebral disc, Short term management

INTRODUCTION

Lumbar epidural steroid injections have been used as part of the conservative management of sciatica due to disc herniation for more than 50 years and are extremely popular in everyday clinical practice. The lumbar epidural space is accessible either by caudal, inter-laminar, or transforaminal routes [1]. Caudal epidural injection has numerous advantages such as a lower risk of dural or subarachnoid penetration, efficacy in multilevel disc prolapse and greater ease of execution in patients with a history of previous spinal surgery. In previous studies of caudal epidural injections, the most common immediate adverse events were transient headache (3.1–3.5%), vasovagal reaction (0.8–2.5%), exacerbation of the low back or nerve root pain (0.4–5%), and facial flushing (2.3–2.5%) [2].

For the caudal approach the most important anatomical landmark is sacral hiatus. The sacral hiatus is formed by incomplete midline fusion of the posterior elements of the fifth or sometimes the fourth sacral vertebra. The remnants of the inferior articular process elongate downwards on both sides of the sacral hiatus and are called the sacral cornua (horns) [3].

In everyday practice, several methods are available for identifying the sacral hiatus and ensuring that the needle is in the proper position. The landmark method involves identifying the depression of sacral hiatus by palpation. The equilateral triangle formed between the two posterior superior iliac spines and the apex of the sacral hiatus helps us in determining the location of the sacral hiatus [Table/Fig-1a,b]. The 'sacral dimples' or 'dimples of venus' that mark the position of the posterior superior iliac spine



[Table/Fig-1a,b]: Illustration to identify the sacral hiatus (by Dr. Jaydeep Nandi).

are at level with the second sacral vertebral spinous process and corresponds with the termination of dura as well as subarachnoid space [4].

A reliable method for confirming proper needle position is fluoroscopic guidance with or without epidurography [1]. In the present study, caudal epidural steroid injection was given without fluoroscopic guidance as inaccuracy of blind caudal epidural injection may be reduced by easy identification of anatomic landmarks and absence of palpable subcutaneous air over the sacrum to 9% [5]. Also, epidurography is not a common practice, and in our study the epidural space was probably equally missed in the two intervention groups.

Volume of corticosteroid solution to be injected had varied among different studies. The total volume injected into the sacral hiatus ranges across studies from 5 to 25 ml and more than 20 ml is usually sufficient to fill the epidural space up to the last lumbar vertebras [4,6]. A study of methylprednisolone dosage in patients with chronic lower back pain found that a 40 mg dose is just as

effective as an 80 mg dose in improving disability. The lower dose should be considered for patients who receive repeat injections and higher for single injection, as in our study [7]. North American Spine Society Guideline of 2007 recommends against a 'Series' of injections where typically three injections were performed at 24 hour or one week intervals regardless of the patient's symptoms. Rather they recommend for single injection which may be supplemented by additional injections either on patient demand, or when the patient's pain exceeded a preset level [8].

Hence, we planned to study the effectiveness of single shot caudal epidural injection of 80 mg methylprednisolone (volume 20 ml) in comparison to similar caudal epidural injection of isotonic saline in patients of lumbosacral sciatica. There is a postulated efficacy of epidural injections of any product, including isotonic saline through a volume or a "washout effect" within the epidural space [9]. Therefore our control group will help in finding out the true clinical effect of caudal epidural steroid.

AIM

To assess the efficacy of caudal epidural steroid injections in patients of lumbosacral sciatica in comparison to placebo saline injections.

MATERIALS AND METHODS

The randomized double blind placebo controlled study was conducted in the outpatient department of a tertiary care center in Kolkata in a one year period (September 2013 to August 2014). The study protocol was approved by the Institutional Ethical Committee and consents taken from patients.

Individuals of both genders, above 18 years of age were included. History of first or recurrent episode of sciatica (definition of sciatica given below) lasting for 1-6 months and with a pain intensity greater than 40 mm was considered. Sciatica must be caused by single or multiple lumbar disc prolapse confirmed by Magnetic Resonance Imaging (MRI).

Definition of sciatica: Sciatica was defined as the presence of pain in one leg, radiating below the knee, with at least one nerve root compression sign (reproduction of radicular pain by raising the leg or distal paraesthesia or sensory, motor, or reflex deficits compatible with the radicular pain) [9].

Exclusion criteria

1. Mid-sagittal Antero Posterior (AP) diameter of lumbar canal less than 5 mm.
2. Prolapsed disc causing severe symptoms that needs immediate surgical attention like pronounced motor weakness, cauda equine syndrome or bladder bowel involvement.
3. Undergone low back surgery, chemonucleolysis, or nucleotomy.
4. Received previous spinal injection.
5. Psychiatric disorder or patients on tricyclic antidepressants.
6. Acute or chronic uncontrolled medical illness.
7. Pregnant women.
8. History of potential adverse reaction to steroid.
9. Unwilling to participate in the study.

We assumed a success rate of 70% in the treatment group and 40% in the control group, thus considering that a difference in the group achieving success lower than 30% would not be clinically relevant. Considering a two sided test with α level or significance level of 5% and power of 80%, we therefore planned to recruit 49 patients in each group or a total study population of 98 patients. The sample size calculation was done with the help of widely popular 'open epi software' version 3.03 part funded by Bill and Melinda Gates Foundation.

The initial evaluation consisted of detail medical history with attention directed at the characterization of pain, identification of relevant co-morbidities, history of spinal treatment, detailed neurological examination, Straight Leg Raising (SLR) Test, assessment of pain and disability index. X-ray and MRI of Lumbo-sacral spine were taken. Routine blood investigation included blood count, bleeding time, clotting time, hemoglobin level, Erythrocyte Sedimentation Rate (ESR) and blood sugar level to rule out any infection or bleeding disorders prior to spinal intervention.

Randomization was done after written informed consent and initial evaluation of the study participants. Before the study began the assessing doctor prepared two sets of 49 cards with either 'A' or 'B' written over it. The cards were randomly sealed inside opaque pre-numbered envelopes. The study participants were serially given an identification number ranging from 1 to 98 and each participant got an envelope with the same serial number.

When the participant submitted his or her envelope to the intervening doctor he carried on the injection procedure as per instruction provided inside the envelope. So the patient and the assessing doctor were both unaware of the treatment received. The intervening doctor was aware about the treatment received but was never a part of the final analysis.

The patients received one injection of either A or B.

A. Steroid group: A 20 ml steroid solution (methyl prednisolone 80 mg diluted in 18 ml of isotonic saline) by a lumbar caudal approach using landmark method combined with loss of resistance technique, without fluoroscopic guidance. Methyl prednisolone has less chance of occluding a blood vessel even if the compound is inadvertently injected intravascularly due to its smaller particulate size. Hence, it was chosen for the study instead of longer acting congeners like betamethasone or triamcinolone which also have larger size.

B. Saline group: A 20 ml of isotonic saline by same lumbar caudal approach.

We followed the landmark method with loss of resistance technique described by Bentley A et al., in Pain Physician Journal [6]. Lumbar exercises, lumbar traction and other spinal injections were not allowed during the study. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) were authorized only 4 weeks after the injection. Paracetamol, hot fomentation, local analgesic ointment and lumbar belts were allowed.

The primary outcome measure was binary i.e., either success or failure of the treatment. Participants themselves rated the perceived degree of overall improvement or deterioration on a descriptive four item scale (recovery, marked improvement, slight improvement, or worse). Patients rating the improvement as "recovery" or "marked improvement" were considered as success. Patients rating the improvement as "slight improvement" or "worse" were considered as failure. If the participant required NSAIDs before week 4, that was also categorized as failure. Pain on a Visual Analog Scale (VAS), the SLR test, Schober test [10], Oswestry disability index (Fritz-Irrgang and Hudson-Cook) [11] and the Roland-Morris index [12] were also assessed as part of secondary outcome measure. Evaluation of participants was done at baseline, 4 week and 12 week by the assessing doctor.

STATISTICAL ANALYSIS

Sample size calculation mandated recruitment of 49 patients in each group. Data were analysed according to per protocol analysis i.e., analysis restricted to only those participants who fulfill the protocol in all respect. Missing data were given a value by multiple imputation method (collecting information about reason for drop-out; and, if possible, following up on drop-outs and obtaining efficacy outcome data). Success rates were compared by a χ^2 test, and a 95% confidence interval around the difference in success

rates was also estimated. For continuous end points, the mean change from the baseline was estimated and the treatment effect was defined as the difference between these changes. Confidence intervals of these treatment effects were then estimated.

Statistical analysis was performed using 'open epi software' version 3.03 (updated on 22.09.2014), an open and free source software for epidemiologic statistics.

RESULTS

Ninety eight patients (minimum age 21 years and maximum age 71 years) were enrolled in the study of which 49 patients were in the steroid group and 49 patients in the saline group. On analysis according to protocol 5 patients were excluded as they were lost to follow up before 4 weeks (2 in the steroid group and 3 in the saline group, all due to failure). Since we followed a per protocol analysis, the total number of patients was 47 in steroid group and 46 in saline group. [Table/Fig-2] shows unambiguously that both the groups (steroid and saline) were almost identical with respect to the baseline characteristics before any interventions.

	Steroid (n=47)	Saline (n=46)
Age (years), mean (SD)	43.04(13.34)	42.85(12.98)
Male sex (%)	28(59.6)	26(56.5)
VAS (0-100mm), mean (SD)	69.09(13.88)	67.43(11.45)
SLR test (degrees), mean (SD)	48.4(17.67)	45.65(16.35)
Schober's test (cm), mean (SD)	2.41(0.46)	2.43(0.44)
Rolland-Morris Index (0-24), mean (SD)	17.17(2.58)	17.09(2.17)
Oswestry Disability Index (0-100), mean (SD)	46.45(5.32)	46.35(4.40)

[Table/Fig-2]: Baseline characteristics.

	At 4 week		At 12 week	
	Success	Failure	Success	Failure
Steroid group (n=47)	32 (68.09%)	15 (31.91%)	28 (59.57%)	19 (40.43%)
Saline group (n=46)	8 (17.39%)	38 (82.61%)	22 (47.83%)	24 (52.17%)
Intergroup difference	50.69%	-	11.75%	-
95% CI for the difference	33.44 to 67.94	-	-8.38 to31.88	-
Number needed to treat/harm	2		9	-
p-value	0.00	-	0.25	-

[Table/Fig-3]: Primary end point (success/failure).

Clinically significant side effect occurred in 3 participants (all in the steroid group). Backache and hypotension occurred in two patients and headache in the day after injection in one patient.

On analysis at 4 weeks, the two groups differed significantly with respect to the primary outcome: among the 93 patients, 8/46 (17%) in the saline group and 32/47 (68%) in the steroid group (p=0.000) were considered as success (difference 50.7%; 95% CI for the difference 33.4 to 67.99). But at the end of the study (week 12) there was no significant difference in primary outcome between the groups: 22/46 (48%) patients in the saline group and 28/47 (60%) in the steroid group (p=0.25) were considered as success (difference 11.8%; 95% CI for the difference -8.38 to 31.9). Hence, though beneficial at 4 weeks, Caudal Epidural Steroid Injection (CESI) is no more superior to placebo injection according to the more stringent primary outcome criteria at 12 weeks [Table/Fig-3].

{95% CI for the difference (also known as absolute risk reduction) should begin and end in either positive or negative number to have beneficial treatment effect. But, if it starts from a negative number and ends in a positive number or vice versa then the treatment can harm a few patients. The Number Needed to Treat (NNT) at 4 weeks for steroid group is 2. This means that about 1 in every 2 patients will benefit from the treatment. Similarly, the Number needed to harm (NNH) at 12 weeks for steroid group is 9. This means that about 1 in every 9 patients will be harmed by the treatment}.

At both 4 and 12 weeks younger patients are significantly more susceptible to failure in either of the groups. We found that at 4 weeks the mean age of failure was 36.73 years while that of success was about a decade older i.e., 46 years among the steroid group (difference 9.27 years; 95% confidence interval of the difference 1.24 to 17.30). Similarly at 12 weeks the mean age of failure was 36.11 years but success achieved at a mean age of around 47.75 years (difference 11.64 years; 95% confidence interval of the difference 4.36 to 18.92). The tendency was no different among saline group patients. Overall results suggested that selecting somewhat older patients as target candidate for CESI is more beneficial for both short and long term outcome [Table/Fig-4].

At 12 weeks wider canal diameter was significantly associated with success in both the groups (Steroid group mean difference 2.54 mm; 95% confidence interval of the difference 1.29 to 3.79: Saline group mean difference 2.47 mm; 95% confidence interval of the difference 1.58 to 3.36). At 4 week only steroid group

	At 4 week		At 12 week	
	Age in years {mean (SD)} in steroid group	Age in years {mean (SD)} in saline group	Age in years {mean (SD)} in steroid group	Age in years {mean (SD)} in saline group
Success	46 (13.85) (32/47)	58.5 (7.35) (8/46)	47.75(13.78) (28/47)	52.00(10.37) (22/46)
Failure	36.73 (9.87) (15/47)	39.55 (11.43) (38/46)	36.11(9.19) (19/47)	34.46 (8.84) (24/46)
Mean difference (success minus failure)	9.27	18.95	11.64	17.54
95% confidence interval	1.24 to 17.30	10.42 to 27.48	4.36 to 18.92	11.83 to 23.25
p-value	0.02	0.0001	0.002	0.0001

[Table/Fig-4]: The comparison of outcome at 4 and 12 weeks against the age of the patients.

	At 4 week		At 12 week	
	Canal diameter in mm {mean(SD)} in steroid group	Canal diameter in mm {mean(SD)} in saline group	Canal diameter in mm {mean(SD)} in steroid group	Canal diameter in mm {mean(SD)} in saline group
Success	11.72 (2.28) (32/47)	12.38 (1.85) (8/46)	12.05 (1.93) (28/47)	12.70 (1.36) (22/46)
Failure	9.54 (2.07) (15/47)	11.21(1.92) (38/46)	9.51(2.30) (19/47)	10.23 (1.62) (24/46)
Mean difference (success minus failure)	2.18	1.17	2.54	2.47
95% confidence interval	0.78 to 3.58	-0.33 to 2.67	1.29 to 3.79	1.58 to 3.36
p-value	0.003	0.12	0.0002	0.0001

[Table/Fig-5]: The comparison of outcome at 4 and 12 weeks against the canal diameter.

	At 1 month		Crude change from baseline				Treatment effect (95% confidence interval)	Statistical significance (p-value)
	Steroid n=47 (SD)	Saline n=46 (SD)	Steroid n=47 (SD)	Statistical significance	Saline n=46 (SD)	Statistical significance		
Pain VAS (mm)	39.51(19.00)	55.74 (15.34)	-29.57 (16.98)	Yes	-11.70 (13.57)	Yes	-17.87 (-24.21 to -11.53)	Yes (p=0.0001)
SLR test (degree)	58.51(16.48)	45.98(17.47)	10.11(13.49)	Yes	0.33(10.02)	No	9.78 (4.87 to 14.68)	Yes (p=0.001)
Schober's test (cm)	2.88 (0.59)	2.62 (0.52)	0.47 (0.38)	Yes	0.19(0.30)	Yes	0.27 (0.13 to 0.41)	Yes (p=0.0002)
Roland Morris Index	12.23 (4.27)	15.50 (3.17)	-4.94 (4.20)	Yes	-1.59 (2.64)	Yes	-3.35 (-4.80 to -1.90)	Yes (p=0.0001)
Oswestry Disability Index	35.77 (8.66)	42.54(6.51)	-10.68 (8.41)	Yes	-3.80(5.58)	Yes	-6.88 (-9.83 to -3.93)	Yes (p=0.0001)

[Table/Fig-6]: Secondary end points, 1 month after enrolment including change from baseline.

	At 3 month		Crude change from baseline				Treatment effect (95% confidence interval)	Statistical significance (p-value)
	Steroid n=47 (SD)	Saline n=46 (SD)	Steroid n=47 (SD)	Statistical significance	Saline n=46 (SD)	Statistical significance		
Pain VAS (mm)	34.83 (20.34)	45.78 (23.60)	-34.26 (19.34)	Yes	-21.65 (20.53)	Yes	-12.61 (-20.82 to -4.40)	Yes (p=0.003)
SLR test (degree)	58.94 (20.3)	48.91(21.98)	10.53 (19.82)	Yes	3.26 (14.99)	No	7.27 (0.02 to 14.52)	Yes (p=0.0494)
Schober's test (cm)	3.13 (0.61)	3.10 (0.64)	0.72 (0.49)	Yes	0.67(0.52)	Yes	0.05 (-0.16 to 0.26)	No (p=0.64)
Roland Morris Index	11.51 (5.03)	13.96 (4.09)	-5.66 (4.93)	Yes	-3.13(3.80)	Yes	-2.53(-4.35 to -0.71)	Yes (p=0.007)
Oswestry Disability Index	35.15 (10.19)	40.20 (8.41)	-11.30 (10.05)	Yes	-6.15(8.04)	Yes	-5.15(-8.90 to -1.40)	Yes (p=0.008)

[Table/Fig-7]: Secondary end points, 3month after enrolment including change from baseline.

demonstrated similar significant association (Mean difference 2.18 mm; 95% confidence interval of the difference 0.78 to 3.58). Overall, more the canal diameter more is the chance of success [Table/Fig-5].

For almost all secondary end points intragroup improvement with time was significant at both 4 and 12 week, except SLR in saline group at both evaluation points. For example at 4 weeks, the crude change in Roland Morris Index of steroid and saline group from baseline was -4.94 and -1.59 respectively. The same at 12 weeks was -5.66 and -3.13 respectively. All four values represented statistically significant changes. Thus, both steroid and saline seems to be beneficial [Table/Fig-6,7].

Again, intergroup differences between steroid and saline were also significant (in favour of steroid) in all five secondary outcome criteria's except Schober's test [Table/Fig-6,7] at both evaluation points.

DISCUSSION

Since the publication of Mixter and Barr's landmark paper in the New England Journal of Medicine the prolapsed intervertebral disc has been irreversibly linked with the pathogenesis of sciatica [13]. The presence of pain was initially ascribed to pressure on nerve roots. This idea was challenged by Kelly and later on by Lindahl et al., who found evidence of an inflammatory response on lumbar nerve roots which paved the way for epidural steroid injections as an important therapeutic tool [13,14].

A meta-analysis of 11 trials (907 patients) on the use of Lumbar ESI (LESI) for sciatica revealed the odds ratio for short-term benefit (up to 60 days) was 2.61 (95% CI 1.9–3.77), compared with placebo. But the odds ratio for long-term benefit was reduced to 1.87 (95% CI 1.31–2.68). This beneficial effect was independent of the route of injection [15]. In the present study also; 4 weeks (short term) follow up revealed caudal ESI to be more effective according to both primary and secondary outcome measures. But at 12 week (long term) caudal steroid injection is no more superior to saline injection according to the more stringent primary outcome criteria although steroid group still showed significant efficacy as per the secondary outcome criteria's. The postulated reasons behind this outcome include:

a) The secondary outcome criteria are sensitive enough to detect even small treatment effect of steroid over saline. Up to 12 weeks the disabling LBP and radicular compression/inflammation signs improved more after steroid injection and hence secondary criteria showed better efficacy in favour of treatment group.

b) But the primary outcome criteria are quite stringent. So at 4 weeks, steroid group patients were more or less pain and symptom free but at 12 weeks most of them had recurrence of mild annoying cramps in calf and glutei region and to get pain relief they required NSAIDs. As 'success' means no intake of NSAIDs, hence the success rate of treatment group as per primary outcome criteria drops down at 12 weeks.

c) Natural history of sciatica is such that most people improve over time even if only placebo or no treatment is given. Also, there may be a role of 'wash out' effect of normal saline [9]. This probably explains a significant percent of saline group of patients having treatment success at 12 weeks.

Verbiest et al., defined relative spinal stenosis as a AP diameter between 10 and 12 mm whereas absolute stenosis was a diameter less than 10 mm [16]. This method has been criticized by some for ignoring the trefoil shape of the lumbar canal but is still widely practiced and used in our study too [17]. We found that wider canal diameter is significantly associated with success in both the groups at 12 weeks. But, at 4 week only steroid group demonstrated similar association. The mean canal diameter of successful patients in steroid group at 4 weeks is 11.72 mm (relative stenosis) while that of failure group is 9.54 mm (absolute stenosis). This implies that CESI may be beneficial for herniated disc associated sciatica but not so much for lumbar canal stenosis. Two RCTs and one blinded observational study met eligibility criteria for lumbar canal stenosis, and none showed positive short or long-term benefit on pain [18,19].

At both 4 and 12 weeks younger patients were more susceptible to failure according to primary criteria in either of the groups. We propose few explanations for this interesting outcome. Older patients are more likely to follow advices. They are sedentary workers with less chance of strenuous activities. Also, they have anatomically smaller sacral canal volume leading to proportionately more steroid reaching the prolapsed disc. Last but not the least; younger patients eventually underwent surgery rather than continuing conservative management.

LIMITATION

The major limitation of our study was lack of fluoroscopy guidance during caudal epidural steroid injections. Moreover, we did not repeat steroid epidural injections as per the recommendations

of North American Spine Society Guideline of 2007 but a recent study mentioned that some patients might benefit from repeated injection [20].

CONCLUSION

Hence, we can conclude that caudal epidural steroid injections can be an important component of short term management of herniated disc associated painful lumbosacral sciatica but not so much for lumbar canal stenosis. Also older patients can expect better outcome. But, CESI does not provide any additional improvement over placebo in the natural history of sciatica as we can observe on longer follow up.

CONTRIBUTION OF AUTHORS

1. Dr. Jaydeep Nandi: Patient management and writing of the manuscript. Will act as guarantor and communicating author.

2. Dr. Abhisek Chowdhery: Review of literature and drafting of the manuscript.

ABBREVIATIONS

1. LBP: Low Back Pain
2. PIVD: Prolapsed Intervertebral Disc
3. ESI: Epidural Steroid Injection
4. LESI: Lumbar Epidural Steroid Injection
5. CESI: Caudal Epidural Steroid Injection
6. PSIS: Posterior Superior Iliac Spine
7. USG: Ultrasonography
8. MRI: Magnetic Resonance Imaging
9. LS: Lumbo-Sacral
10. AP: Antero-Posterior
11. VAS: Visual Analog Scale
12. SLR: Straight Leg Raising
13. NSAID: Non Steroidal Anti Inflammatory Drugs
14. CI: Confidence Interval
15. SD: Standard Deviation
16. ODI: Oswestry Disability Index
17. RMI: Rolland Morris Index.

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