Role of Caudal Epidural Injection in Managing Failed Back Syndrome: One Year Follow Up Result of A Randomized Study

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ABSTRACT

Introduction: There is an increasing prevalence of low back pain in the modern era, which is associated with wide range of diagnostic and therapeutic modalities. The Spine Patient Outcomes Research Trial (SPORT) have demonstrated vast improvement in patients who have undergone surgical interventions compared to conservative treatment modalities. The present study is a one year follow up of 112 patients of post lumber surgery syndrome who suffered from chronic low back and lower extremity pain after being surgically treated for the same.

Material and Methods: This prospective randomized study included 112 patients. They were divided into two groups of 56 patients each.Group I received 0.5% lignocaine, 10 mL; Group II received 8 mL of 0.5% lignocaine mixed with 2 mL of methylprednisolone. The multiple outcome measures included the numeric rating scale, the Oswestry Disability Index assessments at 3, 6, 12 months posttreatment.Atleast 50% improvement in pain and Oswestry Disability Index scores was considered as primary outcome. Successful response was considered only in cases of positive response to the first 2 procedures with at least 3 weeks of relief. All others were considered as failures.

Results: Overall in Group I, 55% of the patients and in Group II, 61% of the patients, showed significant improvement with reduction in pain scores and disability index at 12 months. The results in the successful group showed that at the end of the first year patients experienced approximately 28.5 and 30.7 weeks of relief in group I and group II respectively. The average procedures in the successful groups were at 3.5 in one year.

Conclusion: Caudal epidural injections of local anesthetic with or without steroid is an effective alternative to treat patients with chronic persistent low back and/or lower extremity pain in patients with post lumbar surgery syndrome.

Keywords: Lignocaine, Methylprednisolone, Oswesrey Disability Index, Post Lumbar Surgery Syndrome,

INTRODUCTION

There is anincreasing prevalence of low back pain in the modern era, which is associated with wide range of diagnostic and therapeutic modalities.[1-5] Surgical interventions are increasingly being performed for spinal stenosis, degenerative spondylolisthesis, intervertebral disc herniation apart from the usual conservative modalities of treatments and interventional modalities.[6-9] The Spine Patient Outcomes Research Trial (SPORT)[10] have demonstrated vast improvement in patients who have undergone surgical interventions compared to conservative treatment modalities. The studies have shown a significant decrease in reoperation rate ie 4% at one-year and 10% at 4 years. Further, the literature is full of numerousevaluations illustrating a 9.5% to 25% reoperation rate.[11-13] There were various reasons for repeat surgery like herniated disc, stenosis, disc degeneration, spondylolysis, spondylolisthesis, and scoliosis.[14-15] However, conditions like epidural fibrosis, sacroiliac joint pain, disc herniation, discogenic pain, spinal stenosis, and facet joint pain are amongst many conditions which do not require repeat surgery amd are managed by interventional techniques that are responsible for continued persistent pain and disability include.[16-18] Epidural fibrosis is a widely known major complication after lumber spine surgery but its role in peridural scarring in recurrent radicular pain is still controversial. According to Ross et al[13] epidural fibrosis patients are at a 3.2 times higher risk of recurrent radicular pain than those with less scarring. According to some experimental studies there is a electrophysiological evidence of neurologic disturbances which is caused by peridural scar formation.[18] Mechanical tethering of nerve roots has been seen in the vertebral canal caused by epidural fibrosis.[19,20] Disturbances in blood flow[21] and painful responses triggered by the release of proinflammatory cytokines cause irritation of the exoposed dorsal root ganglion.[22] Osteopontin is regarded as the major culprit in forming epidural fibrosis and the dorsal root ganglion response to peridural scar formation.[17] Consequently, epidural fi-brosis may be a causative factor in at least 20% to 36% of all cases for failed back surgery syndrome.[12,13] Epidural steroid injections and adhesiolysis are two of the most commonly utilized interventions for managing long term, continuous pain in lower back/ lower extremity after lumber surgery syndrome which could be because of various causes, including epidural fibrosis, spinal stenosis, recurrent disc herniation, and discogenic pain without evidence of facet joint pain, radiculitis, or sacroiliac joint pain.[23-25] But the use of epidural injection has been associate with many controversies and has faced criticism for its use in all the above indications majorly due to lack of clinical evidence.[24-27] Some evidence of justification is present regarding its use in managing post lumber surgery syndrome.

The present study was a one year follow up of 140 patients of post lumber surgery syndrome who suffered from chronic low back and lower extremity pain after being surgically treated for the same.

MATERIAL AND METHODS

Total 112 patients were selected from two centers and were assigned to one of 2 groups. The patients were divided into a

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How to cite this article: Kapil Bansal, Anshul Dahuja, Sabyasachi Bhowmik, Mamta Gupta, Rashmeet. Role of caudal epidural injection in managing failed back syndrome: one year follow up result of a randomized study. International Journal of Contemporary Medical Research 2017;4(1):208-211.

group of 56 each. Group I patients caudal epidural injections of local anesthetic (lignocaine 0.5%)10ml; the 56 patients assigned to Group II received caudal epidural injections of 0.5% lignocaine 8 mL mixed with 2 mL of methylprednisolone. This 10 ml injection was followed by a 3 ml injection of 0.9% sodium chloride solution to remove all the contents from the sacral canal. All the preoperative data was collected from the patients. It included demographic data, medical history, surgical history. All the required radiological and physical examination was performed prior to the surgery. Patients were asked to rate their pain on Numeric Rating Scale and functional status was assessed using Oswestry Disability Index 2.0 (ODI). The funding for the present study was by internal sources of the practice. There was no external funding from any industry or elsewhere. Patients with a history of chronic function-limiting low back pain with or without lower extremity pain of at least 6 months duration after surgery, patients above the age of 18 years, patients mature enough to understand the study protocol, patients without any diagnosed facet joint join pain and patients who failed to improve using conservative treatment but not limited to physical therapy, chiropractic manipulation, exercises, drug therapy, and bedrest were included in the study. Patients with uncontrolled use of opoids, uncontrolled psychiatric disorders or medical illness, any condition interfering with the interpretation of the outcomes, pregnancy or lactating women or patients allergic to local anaesthetic or steroids were not included in the study. Two surgeons performed the caudal epidural procedures in a sterile operating room at two respective ambulatory surgery centers. All the procedures were performed with patients in the prone position with appropriate monitoring and intravenous sedation with midazolam as indicated. Injection of nonionic contrast medium in a sterile fashion confirmed epidural space. After confirmation appropriate mixture was given according to the group. Patients feeling any kind of relief from first injection interms of physical and functional status received second injection. The repeat injections were given only when increased levels of pain were reported with deteriorating relief below 50%. No additional intervention was given to any patient. Their previous drug therapy, therapeutic exercise program, and work were all continued; however, there were no specific additional interventions were continued during the entire study. Both pain (0 – 10 scale) and disability (0 – 50) scale were assessed at an interval of 3, 6, 12 months post treatment. The reliability of the NRS and ODI have been established. Long lasting improvement with significant pain relief and decreased disability status of 50% or more was utilized. A significant and persistent relief with the first and second procedure and minimum of 2 weeks with the first 2 procedures, the epidurals were considered to be successful; all others were considered failures.

STATISTICAL ANALYSIS

Chi square test was applied as a test of significance, if the value was less than 5, then fisher's exact test was applied. To compare pre and post treatment results of pain and disability a paired t test was applied. A *P* value of 0.05 was regarded as significant.

RESULTS

The recruitment period lasted from January 2013 to November 2015. Table 1 illustrates each groups baseline demographic and clinical characteristics 39% male in gp 1 and 51% in gp II where as 61% female in gp 1 and 49% in gpII. Mean age in gp1 51.2 and 47 ± 12.3 in gp II, where as non significant diffrences in weight and hieght. 42% population injured in gp1 and 55% in gp II. Mean Successful Participants (35.1 ± 14.5)

		gp1		gp II	
Sex	**Male**	**39% (23)**		**51% (29)**	
	Female	61% (33)		49% (27)	
Age	Mean ± SD	51.2 ± 14.1		47.0 ± 12.3	
Weight (pounds)	Mean ± SD	190.5 ± 46.8		177.2 ± 41.8	
Height (cm)	Mean ± SD	165.8 ± 3.6		164.1 ± 3.7	
Duration of Pain (months)	Mean ± SD	159.1 ± 106.9		164.7 ± 113.3	
Onset of the Pain	Gradual	58% (32)		45% (26)	
Injury	42% (24)			55% (30)	
Low Back Pain Distribution	Bilateral	70% (38)		65% (37)	
Left or Right		30% (18)		35% (19)	
Surgical Interventions	Discectomy or Laminectomy	65% (37)		65% (37)	
Fusion		35% (19)		35% (19)	
Number of Surgeries	One	70% (38)		65% (37)	
Two		30% (18)		35%(19)	
Numeric pain Rating Score	Mean ± SD	7.4 ± 1.0		7.6 ± 0.9	
Oswestry Disability Index	Mean ± SD	32.3 ± 4.5		30.1 ± 4.5	
		Successful Participants		**Failed Participants**	
		Gp I (42)	**Gp II (44)**	**Gp I (14)**	**Gp II (12)**
Average number of procedures per one year		4.0 ± 1.0	4.1 ± 1.0	1.25 ± 0.5	1.5 ± 0.8
Total number of procedures in one year		187	194	21	23
Total relief per one year (weeks)		35.1 ± 14.5	38.9 ± 13.2	2.4 ± 3.6	2.1 ± 3.3
Successful participant - At least ≥ 3 weeks relief with first 2 procedures.					

Table-1: Baseline demographic and clinical data

Serial Number	Numeric Pain Rating Score (Mean ± SD)		Oswestry Disability Index (Mean ± SD)	
	Group I (56)	Group II (56)	Group I (56)	Group II (56)
Baseline	7.4 ± 1.0	7.6 ± 0.9	32.3 ± 4.5	30.1 ± 4.5
3 months	4.0 ± 1.8	3.9± 1.7	15.6 ± 6.3	15.2 ± 6.8
6 months	4.2 ± 1.9	4.1 ± 1.7	17.1 ± 6.9	16.1 ± 7.0
12 months	4.5 ± 1.9	4.2 ± 1.7	17.9 ± 6.9	16.5 ± 7.0
Significant improvement is >50 %reduction in NPRS and Oswestry disability index at the end of 1 year.				

Table-2: Comparison of Numeric Rating Scale for pain and Oswestry Disability Index score summaries at four time points.

of gp I and Successful Participants Mean (38.9 ± 13.2) of gp II Mean failed(2.4 ± 3.6) of gp I and failed Participants Mean (2.1 ± 3.3) of gpII. Treatment providing relief for atleast 3 weeks were successful. In the form of Pain Relief and Functional Assessment. Table 2 presents the results of repeated measures analysis. Regarding pain scores and Oswestry Disability Index for functional status.

Adverse Events: There was no evidence of any adverse reaction occurring over a period of 1 year in any of the 112 participants.

DISCUSSION

This randomized controlled trial showed a significant improvement in pain and functional status at the end of follow up period of one year, indicating that epidural injection of steroids in patients of post lumber surgery syndrome play an effective role. The results of this practical evaluation demonstrate that if carefully selected patients who do not have facet joint pain show a significant improvement in pain and functional status. In our study 55% patients in Group I and 61% patients in Group II show improvement at the end of one year. Thus caudal epidural injection are a successful treatment modality in treating patients of post lumbar surgery syndrome. The response thus obtained was similar to patients receiving local anesthetic only or local anesthetic and steroid combination with methylprednisolone. Effective pain relief(in weeks) in successful participants was 28.5weeks in Group I and 30.7 weeks in Group II at the end of one year. Further, the result of average pain relief per procedure for the initial 2 procedures, as well as subsequent procedures and overall procedures over the period of 1 year was similar in both groups.

The average number of procedures at the end of one year came out to be approximately 3.5.

The literature is replete with multiple studies and systematic reviews in favor and against epidural injections.[28-33] By far no studies have been done at this large scale to determine the effectiveness of fluoroscopically directed caudal epidural injections in pain management. Multiple studies have been criticized, most importantly for their design and their inability to confirm the location of the injectate by not using fluoroscopy.[34-37] there has been various criticizes on multiple systematic reviews for their methodology by evaluating studies inappropriately, thus, reaching inaccurate conclusions based on inappropriate evidence synthesis.[34,38]

A systematic randomized and non randomized study conducted by Conn et al[36] for managing chronic low back pain of post-surgery syndrome along with other conditions with a follow up period of 6 months. Due to paucity of literature, the evidence was regarded as Level II-2.[37] However various systemic reviews that have been performed have combined multiple approaches into one, but most of them performed without fluoroscopy.[6,7]

This study lacks placebo group. However placebo group comes with its own set of problems in interventional technical studies. It yields highly variable results. In many previous studies local anaesthesia and steroids have yielded similar results[28-34] but in our study steroids have taken an edge due to their anti-inflammatory action. The mechanism of action of both local anaesthetic and steroids has been discussed by many authors in their reviews.[6,25-27]

In summary, the evidence shown in this 1-year evaluation of a randomized, active control, double blind trial demonstrates that caudal epidural injections in patients with post lumbar surgery syndrome with chronic, persistent, low back or lower extremity pain provides significant relief. Consequently, selected patients may be offered caudal epidural injections with or without steroids on a long-term basis with steroidal injections taking an edge but larger follow up is required to make a definitive statement.

CONCLUSION

The one-year results of this randomized, double-blind, active controlled trial of epidural effectiveness for post lumbar surgery syndrome illustrates 55% of patients receiving local anesthetic and 61% of patients receiving local anesthetic and steroids showed a great deal of improvement in pain relief and functional status. But statistically when comparing two groups, there was no significant difference between them.

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 25-12-2016; **Published online**: 07-02-2017