

Functional Outcome of Caudal Epidural Steroid and Transforaminal Epidural Steroid Injection in Lumbar and Lumbosacral Radiculopathy: an Observational Study

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Abstract

Introduction: Chronic low back pain with or without leg pain is a major socioeconomic burden worldwide. It is often associated with poor quality of life. Approximately 40% of patients with chronic low back pain have associated neuropathic element. Diagnosis and treatment of neuropathic pain has often being challenging as it is poorly understood and often missed by the treating physician. In addition to surgery, various non-invasive modalities of treatment such as short term bed rest, aetio-pathology targeted physiotherapy and lumbar epidural steroid have been advocated. The efficacy of lumbar epidural steroid is debatable though evidences suggest transforaminal epidural steroid injection (TFESI) is more efficacious than inter laminar or caudal epidural steroid injection (CESI).

Materials and Methods: 67 patients who underwent either caudal epidural steroid injection or transforaminal epidural steroid injection in a tertiary care centre from 01.01.2019 to 31.12.2020 were included in the present study. The relevant medical data of these patients were retrieved from the hospital medical record department. Two outcome measures namely Visual Analogue Scale (VAS) for leg pain and walking distance were analyzed before the procedure and following 3 weeks, 3 months and 6 months after injection. The data were analyzed using SPSS 20 software.

Aim and objectives: To observe the difference in functional outcome between caudal epidural steroid injection and transforaminal epidural steroid injection in lumbar and lumbosacral radiculopathy.

Results: 67 patients with male female ratio being 1.09:1. The average of the study population was 45.13 years. There were 10 cases at L3L4, 7 cases at L3L4L4L5, 27 cases at L4L5, 5 cases at L4L5L5S1 and 18 cases at L5S1. There were 30 cases of PIVD, 23 cases of disc bulge with lateral recess stenosis, and 14 cases of Lumbar Spinal Stenosis (LSS). TFESI is more effective than CESI group, both in reduction of VAS and increasing walking distance at 3 weeks (p 0.396, p 0.1624) 3 months (p 0.0297, p 0.497) and 6 months (p 0.0095, p 0.0024) post injection.

Discussion: Retrospective study, comprising 67 patients, equally matched age and sex. Two outcome measures were analyzed. There was significant decrease in VAS and improvement of walking distance in both CESI group and TFESI group, at 3 weeks, 3 months and 6 months post injection. There was more significant improvement in TFESI group than CESI group. There was a single major and a few minor complications in this study.

Conclusion: Transforaminal epidural steroid injection is more effective and for longer duration than caudal epidural steroid injection in lumbar and lumbosacral radiculopathy.

Keywords: Lumbar, Radiculopathy, Caudal, Transforaminal, Epidural, Steroid, Injection.

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Introduction

Chronic Low Back Pain (LBP) is a major health problem globally [1]. The incidence increases manifold in developing world as the population is young and often do heavy strenuous work to cope up the infrastructural development. India tops the chart with increasing number of young patients presenting with chronic low back pain and is often accompanied by loss of man hours and consequent decrease in productivity of the workforce. Chronic low back pain and accompanying leg pain is considered a mixed pain syndrome with combination of nociceptive and neuropathic mechanisms [2,3]. The leg pain is widely believed to be a neuropathic disorder with nociceptive mechanism playing predominant role in low back pain [3]. The reported prevalence of neuropathic pain is approximately between 36% to 55% [4,5,6]. Vast majority of patients with chronic neuropathic LBP experience poor quality of life, and meet higher health care costs [7, 8, 9].

Lumbosacral radiculopathy, also known as sciatica, is described as radiating pain along the lower limb that follows a definite dermatomal distribution, with/without any associated sensory and/or motor deficit [10]. It is the commonest cause of neuropathic pain in patients with back related pain. The etiology in vast majority of cases is due to compression or irritation of nerve roots in lower back. The primary pathological entity being intervertebral disc prolapse and Lumbar Spinal Stenosis (LSS), secondary to degeneration of the disc, vertebral bodies and along with the thickening of ligamentum flavum [11].

Various modalities of treatment are being advocated to treat lumbar radiculopathy with back pain. Most common methods adopted are short-term bed rest, topical and systemic NSAIDs, neuromodulators and aetiopathology targeted specific physiotherapy. Surgical options are reserved for non/poor responders or patients with neurological deficit.

Epidural steroid is fast evolving as a non-invasive modality of treatment and it gives immediate relief of both back and leg pain though the duration of pain relief is short. Several approaches are available to access the lumbar epidural space such as caudal, inter laminar, and transforaminal approach. Injecting through transforaminal approach is also known as selective nerve root block (SNRB) or selective epidural injection. The objective of an epidural steroid injection is to deliver corticosteroid close to the site of pathology, presumably onto an inflamed nerve root. Reports of the effectiveness of epidural corticosteroids have varied from 18% to 70% [12].

However, reports of the effectiveness of transforaminal epidural steroids have shown it to be superior, with outcome data indicating cost effectiveness as well as safety [12]. The aim and the objectives of this present study are to analyze the functional outcomes of two different modalities of epidural steroid injection in lumbosacral radiculopathy.

Materials and Methods:

This is a retrospective study conducted in Kalinga Hospital, Pvt Ltd, Bhubaneswar, Odisha, India for a period of two years from 1st January 2019 to 31st December 2020. Sixty seven (67) cases of lumbosacral radiculopathy were included in this study.

Our inclusion criteria were mostly clinical and supplemented by Magnetic Resonance Imaging (MRI) features. The clinical criteria were; patients with leg pain (lumbar radiculopathy) with or without back pain, combined back pain and leg pain but the predominant component being leg pain, definite sensory/motor or both deficit but the muscle power being not less than grade 4 on British Medical Council (BMRC) grading. The MRI criteria were diffuse disc bulge, disc prolapse, unilateral or bilateral lateral recess stenosis and central lumbar canal stenosis (LCS). However the clinical features should correlate well with radiological features. The exclusion criteria were far too many e.g.

- Motor power less than BMRC grade 4,
- Patients with previous spine surgery, coagulaopathy
- Chronic medical co-morbidities such as uncontrolled Diabetes Mellitus, Hypertension chronic renal failure.
- The patients with poor skin conditions (fungal/bacterial infections),
- Pregnant women and
- Patient not willing for the procedure

Sample Population and Sampling Technique:

78 patients underwent epidural steroid over two years, starting from 1st January 2019 to December 2020. All the patients' data were retrieved from the medical record department. Patients fulfilling the strict inclusion criteria and with post injection protocol were included in the study. The data of the patients listed for the study were evaluated meticulously. The history included age, sex, and duration of low back pain and leg of leg pain, neurogenic claudication pain and the walking distance. The clinical examination included straight leg test, sensory deficit, and motor weakness. The MRI findings were also noted down from the indoor medical records. Only patients with clinical

symptoms and signs correlating with MRI features were included for final analytical study. Patients with proven dynamic instability on roentgenogram were excluded from the study. This study was non-randomized and single blind study.

Functional Evaluation: Two functional outcome measures were taken to assess the results; Visual Analogue Scale (VAS) and Walking distance. The VAS before injection and 3 weeks, 3 months and 6 months post injection were noted down. Similarly, the walking distance in meters before injection and at 3 weeks, 3 months and 6 months post epidural steroid was noted. Any post injections complications and any patient required spinal surgery were also noted. Based on the mode of epidural steroid delivery, the patients were categorized into two groups; Group I: Caudal epidural steroid group, those who received epidural steroid via caudal route and Group II: Transforaminal epidural steroid group, those who received epidural steroid via transforaminal route.

Technical details:

Caudal Epidural Steroid Injection (CESI): The patient was made to lie prone on a radiolucent operating table. Two pillows were used to position the patient. One pillow was placed under the chest and the other under the thigh to make the sacrum hiatus more prominent and horizontal. The patient was cleaned with 10% Betadine (Providone Iodine-Win Medicare Pvt. Ltd) and draped well. The medications to be injected were prepared in advance. A 5 ml disposable syringe filled with 2% Xylocaine [Lignocaine hydrochloride (2%), LOX 2%, Neon Laboratories Ltd, India] for local infiltration. One 5 ml disposable syringe filled with water soluble, nonionic contrast solution Iohexol [Omnipaque, 350 mg/ml, GE Healthcare Inc, McKesson US], 20 ml syringe filled with 2 ml of lignocaine, 8 mg of Inj Dexona [Inj. Dexamethasone sodium phosphate, 4 mg per ml, Zydus Fortiza, Zydus Healthcare Ltd., India], 16 ml of water for injection which totally amounts 20 ml were kept separately. The drugs used in the procedure had added preservatives such as Methylparaben IP (0.15% w/v, and Propylparaben IP (0.02% w/v) in Dexona and Methylparaben IP (1mg/ml) in LOX. We used 22 G spinal needle and the distal 2 cm was bent a little to adjust the curvature of the sacrum. A standard AP view of the sacrum and LS spine was taken to keep the spinous processes equidistant to the pedicles. The sacral hiatus was identified by equilateral triangle method and by manual palpation. Local anesthesia (Lignocaine 2%) was infiltrated at scaral hiatus and the spinal needle was inserted at 45 degrees to the horizontal. Once it is in the canal it is gradually turned 180 degree to follow the curvature of sacrum and it is advanced to the junction of S2 and S3 (Fig 1). The whole procedure was done under

fluoroscopy guidance. The needle position was confirmed in both anteroposterior and lateral views. The contrast was injected through the spinal needle under fluoroscopy to exclude intra spinal or intravascular extravasations (Fig 2, 3). A typical contrast injection gives an inverted Christmas tree appearance (Fig 2) delineating the lumbosacral roots. It is only at this stage the steroid mix was injected slowly over 60 seconds under furoscopy guidance and cardiovascular monitoring.

Transforaminal Epidural Steroid Injection (TFESI): The patient was made to lie down on a radiolucent operating table with one pillow under chest wall and the other on upper thigh. The entire procedure was done under C arm (fluoroscopy) guidance. The patient's lumbo-sacral spine was made horizontal to ground and the spinous processes were made equidistant to both pedicles. Scottie doggie view was obtained by tilting the C arm. The pedicle base identified at 6 'O'clock position. The local anesthetic was infiltrated to skin and the deeper tissues. The spinal tip was bent a little and advanced ventrally and medially such that the needle is at 6 o clock position but inferior to the pedicle in AP view but in the inferior quadrant of the neural foramen in lateral view; Kambini's triangle (Fig 6, 7). A sudden give indicates the needle in epidural space. Once the needle tip position was confirmed, the contrast was injected after negative aspiration for blood or CSF (Fig 6, 7). The contrast delineates the traversing root, the exiting root and once it excludes the extravasations of the contrast to subarachnoid space, or into vessel, the steroid mix is injected (Fig 6, 7).

Post Injection Protocol: The patients were shifted from OT table and kept in post-operative room for observation. After two hours, the patient was discharged with tablet Paracetamol 650 mg. [Calpol, Glaxo Smith Kline Pharmaceuticals Ltd], as and when necessary basis. The patients were reviewed at 3 weeks; 3 months and 6 months post epidural steroid injection. On each visit, the VAS and walking distance were noted. The mean pre-injection VAS, post-injection VAS and the mean pre- & post-injection walking distances were noted.

Statistical analysis: The data were analyzed by SSPS 20 software. A statistical correlation was obtained between two methods of epidural steroids with respect to VAS and walking distance in between two groups. Two t test were done to find out the p value and statistical correlation.

The aim and objectives of the study is to analyze the functional efficacy of two different modalities of epidural steroid injection in lumbosacral radiculopathy.

Results:

There were 67 patients with 35 males and 32 females with male female ration being 1.09:1. There were 33 patients in CESI group and 34 patients in TFESI group. The average age of the patient in CESI and TFESI was 43.55 years and 46.71 years respectively. There were 10 cases at L3L4, 7 cases at L3L4 L4L5, 27 cases at L4L5, 5 cases at L4L5 L5S1 and 18 cases at L5S1. The pathology was Disc bulge with Lateral recess stenosis 23 cases, PIVD 30 cases and 14 cases of mild LSS (table 1).

The average pre injection VAS in CESI and TFESI was 6.03 and 6.06 respectively with very

significant reduction of VAS in both groups at 3 weeks, 3 months post injection in both the groups (table 2). There was significant reduction of VAS in TFESI than CESI group, at 3 weeks post injection (p=0.396), at 3 months post injection (p=0.0297), and at 6 months post injection (p=0.0095) (table 3). There was significant improvement in walking distance in TFESI than CESI at 3 weeks post injection (p 0.1624), 3 months post injection (p=0.497), and 6 months post injection (p=0.0024).

TFESI was more effective than CESI at 3 weeks, 3 months and 6 months post injection (table 4).

Table 1: Demographic profile

	N	M	F	Ave. Age (Years)	SD	Level of Pathology					Type of pathology		
						L3 L4	L3L4, L4 L5	L4L 5	L45, L5S 1	L5S 1	Disc Bulge with Lateral recesses Stenosis	PIVD	LSS
Caudal Epidural Steroid Injection	33	17	16	43.55	12.35	02	03	05	05	18	04	21	08
Transforaminal Epidural Steroid injection (TFESI)	34	18	16	46.71	9.27	08	04	22	00	00	19	09	06

PIVD- Prolapsed Intervertebral Disc, LSS Lumbar Spinal Stenosis

Table 2: VAS and Walking Distance

	Average VAS(for Leg Pain)				Average Walking Distance (meters)			
	Pre Inj	Post Injection			Pre Inj	Post injection		
		3 weeks	3 months	6 months		3 weeks	3 months	6 months
CESI	6.03	2.30	4.00	5.79	742.61	1515.15	1115.15	739.39
SD	1.29	1.24	1.12	1.41	350.52	520.79	292.75	259.73
TEFSI	6.06	1.71	3.41	4.88	811.76	1684.71	1276.47	960.29
SD	1.07	1.09	1.05	1.37	331.90	460.91	362.70	308.41

CESI: Caudal Epidural Steroid Injection, TFESI: Transforaminal Epidural Steroid Injection.

Table 3: Statistical Correlation-VAS CESI Vs TFESI

	t	df	Two tailed P value	Inference
Pre Inj	0.0987	65	0.9217	Not significant and population size is equally distributed
3 week Post Inj	2.0998	65	0.396	Significant TFESI is more effective than CESI as the VAS is lesser that CESI
3 months Post Inj	2.2227	65	0.0297	Significant TFESI is more effective than CESI as the VAS is lesser that CESI
6 months Post Inj	2.6717	65	0.0095	Significant TFESI is more effective than CESI

Table 4: Statistical Correlation-Walking Distance CESI Vs TFESI

	t	df	Two tailed P value	Inference
Pre Inj	0.8295	65	0.4099	Not significant, and the population size is equally distributed.
3 weeks Post Inj	1.4130	65	0.1624	Not significant, CESI and TFESI are equally effective
3 months Post Inj	1.9997	65	0.497	Significant. TFESI is more effective than CESI as walking distance is increased.
6 months post Inj	3.1664	65	0.0024	Significant. TFESI is more effective than CESI as walking distance is increased.

Caudal Epidural Steroid Injection (CESI)

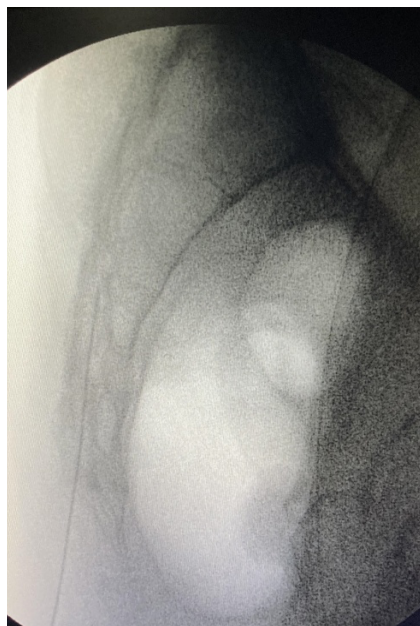


Figure 1: 22G spinal needle in situ



Figure 2: Contrast delineating roots

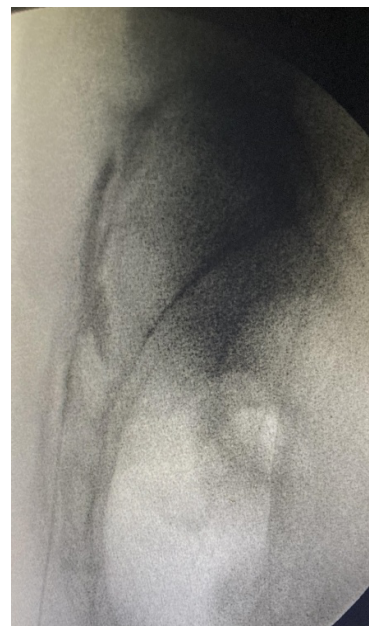


Figure 3: Contrast in Epidural Space at the Junction of S2S3 Vertebrae



Figure 4: Pre injection MRI (Sagittal and Axial Views)



Figure 5: Spondylolisthesis L4L5 Grade 1 with disc bulge and bilateral lateral recess stenosis

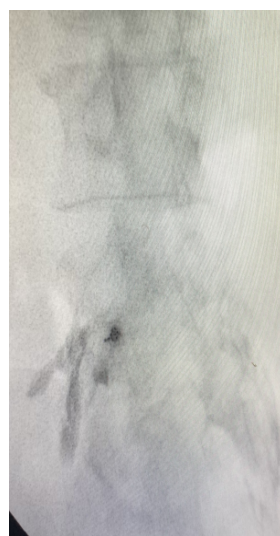


Figure 6: Transforaminal Epidural Steroid (TFESI)

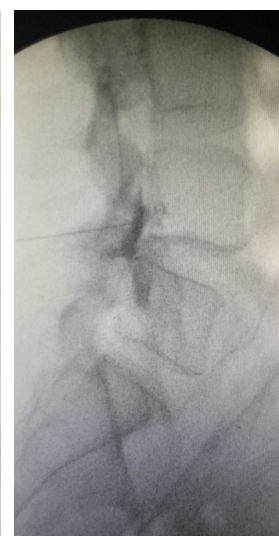


Figure 7: Contrast dye delineating Traversing and Exiting roots

Discussion

The first epidural corticosteroid injection for lumbar radiculopathy was performed by Lievre and associates in 1953¹³. Epidural steroid injection is advocated for lumbosacral radiculopathy. However it is also used in low back pain (LBP)¹⁴ and LBP with radicular pain and lumbosacral radiculopathy secondary to disc prolapse¹⁵, post laminectomy syndrome¹⁶ and Lumbar Spinal Stenosis (LSS)¹⁷.

The efficacy of caudal epidural steroid in lumbosacral radiculopathy is debatable, though most studies have proved good short term results. Literature survey revealed use of steroids such as dexamethosone, betametasonone and triamcinolone acetate, but methyl prednisolone acetate is most commonly used. Salt and water retention has been a problem in all steroids though little lesser in triamcinolone acetate as shown by studies by Delaney and coworkers [18].

Corticosteroid injection reduces the inflammation of nerve roots, decreases the stimulation of dorsal neuron, and suppresses the transmission from the nociceptive C fibres [19]. It also helps in decreasing the cicatrization of the lumbar roots by inhibiting fibrin and collagen deposition.

The use of corticosteroids either undiluted or diluted with isotonic saline with or without local anesthetic agents is still a controversy. In CESI the steroid is diluted with saline in order to make a larger volume to reach up to L3L4 disc space. There have been many theoretical advantages of using local anesthetic drugs; a) immediate pain relief giving psychological benefit to the patients, b) breaks "pain muscle spasm ischemic pain" cycle and improves muscle spasm, c) verifies the presence of corticosteroids in epidural space by presence of sensory epidural blockade, d) decreases associated sympathetic dystrophy, e) anesthetizes the nerves supplying the facet joints.

There has been a further controversy about use of particulate and non-particulate steroid. The Meta analysis by David J. Kennedy et al [20] on 16,000 consecutive epidural steroids found that in majority of transforaminal epidural steroid inject, particulate steroid have been used with very good result but it may be associated with arterial embolization, leading to serious neurological complication.

He also concluded that non-particulate substance like dexamethasone has been equally effective. A larger prospective study conducted in Mayo clinic also opined equal effectiveness of dexamethasone as compared to particulate substance. Some of the authors even do not recommend use of particulate steroid at all especially in transforaminal route.

Demographic Profile:

(Table no 1). This study population was evenly matched in terms of equal number of male and female patients with identical average age of patients in each group. The level of pathology was highest 40.29% (n=27) at L4L5, followed by 26.86% (n= 18) cases at L5S1, 14.92%(n=10) cases at L3L4, 10.44% (n=7) cases at L3L4 L4L5, and the least being 7.46% (n=5) at L4L5 L5S1 level. The maximum pathology was seen at L4L5, L5S1 in CESI. Vast majority of pathology being PIVD (44.77%) followed by disc bulge with lateral stenosis 34.32 % (n=23), and least being LSS 20.89% (n=14). There has been dissension over the volume of infusion, the rate of infusion and the spread of steroid mix [21, 22, 23]. Murphy et al [24] on performing magnetic resonance epidurography concluded that a volume of 10 ml was less likely to be effective for L5/S1 disease in nearly 50% of the patients and that at least 20 ml of infusion was necessary to reach at and above L4/5 level.

The rate of epidural injection is a concern as rapid injection is associated with more complications such as vision loss [25] retinal haemorrhages [26] due to rise in intra cranial pressure. Satit Thiengwittayaporn et al [21] in their study comparing rapid and slow rate of inject concluded that slowly inject is safe and rapid inject has no added advantage over slow inject and is associated with complications. In the present study, in each and every case of CESI, 20 ml of steroid mix was injected over 60 seconds, with no peri-injection complications.

In this study the average pre injection VAS in CESI and TFESI was 6.03 and 6.06 respectively with very significant reduction of VAS in both groups at 3 weeks, 3 months post injection in both the groups. However, the VAS at 6 months post injection in CESI was almost same as pre injection VAS, but in TFESI the VAS at 6 months post injection was still significantly lesser than pre injection level (table 2, 3). In addition to statistical significance a reduction of two grades in VAS was considered significant. Considering statistical correlation, taking one outcome measure namely VAS, there was significant reduction of VAS in TFESI than CESI group, at 3 weeks post injection (p=0.396), at 3 months post injection (p=0.0297), and at 6 months post injection (p= 0.0095). Similarly taking walking distance into consideration, there was significant improvement in walking distance in TFESI than CESI at 3 weeks post injection (p 0.1624), 3 months post injection(p=0.497), and 6 months post injection (p=0.0024) (table 3,4).

In summary, taking two outcome measures into account, TFESI was more effective than CESI at 3 weeks, 3 months and 6 months post injection (table 3,4). Satit Thiengwittayaporn et al [21] on CESI concluded that, there was a significant reduction of VAS and increment of walking distance at 3 weeks, 6 weeks post injection, but at 12 weeks the VAS has increased and the walking distance decreased from 6th week post injection though the VAS and walking distance were lesser than pre injection VAS level.

Similar results were seen in the present study on CESI, but the reduction of walking distance and increment of VAS was seen only after 6 months post CESI as compared to 3 months in study by Satit Thiengwittayaporn et al. This present study is has shown better results on comparing to the study done by Jung Hwan Lee [27] on TFESI Vs CESI. But their study was done only on LDH. Jung Hwan Lee [27] concluded that, TFESI is superior to CESI in terms of longer duration of pain relief up to 6 months with better improvement in NRS and ODI. Whereas in CESI though there is good reduction of NRS and ODI at two weeks, it is not persistent at 3 months post injection.

They also concluded that TFESI has better clinical benefits over CESI. However with low level of evidence and no significant results on met analysis, TFESI could be weakly recommended over CESI. Ackerman et al [15] on three methods of lumbar epidural steroid concluded that, the transforaminal epidural steroid injection was more effective than the caudal or interlaminar injections. Both Ackerman et al [15] and Jung Hwan Lee et al [27] attributed the better functional outcome to a higher incidence of steroid placement in the ventral epidural space when the transforaminal route was used. However both the studies had the limitation of using lumbar epidural steroid only in disc prolapse and not in lumbar spinal stenosis. In this study two patients; both with PIVD L4L5 and the other at L5S1 for which TFESI and CESI were done, had increase leg pain, increased VAS with decrease walking distance at 6 months post epidural steroid, underwent fenestration and microdiscectomy.

Complication(s)

Most studies reveal, minor complications approximately 15.6% per injection. Botwin Keeneath P et al [28,29] in 257 CESI on 139 patients, and 322 TFESI on 200 patients had only minor complications such as insomnia the night of the injection 4.7%, 2.4%-3.5% transient nonpositional headache, 2.4%-3.1% increased back pain, 1.2%-2.3% facial flushing, 0.8% vasovagal reactions, 0.8% nausea, and 0.4%-0.6% increased leg pain. However they did not have a single case of dural puncture in either method.

In this study during CESI 21.21% (n=7) patients complained of transient leg pain during caudal steroid injection which subsided within 5 minutes, 7.46% (n=5) patients complained of pain at sacral hiatus which subsided within 2 days. We did not have any patient with vasovagal attack or hypotension during procedure. However in TFESI group 26.47% (n=9) patients complained of pain at injection site which subsided within 2 to 3 days, 2.94% (n=1) patient in TFESI group, developed of worsening neurology and persistent leg pain. There was no case of infection, or dural puncture in either group.

Clinical Utility:

CESI is a relatively simple, easier procedure and it can be performed as day care procedure in operation theatre or in outpatient department with cardiac monitoring. It can be administered by orthopedic surgeons, spine surgeons and neurosurgeons. It is relatively free of any complications. On the other hand, TFESI needs training, and the procedure to be performed in operation theatre and under better cardiac monitoring. Both the procedures can be performed

for high risk patients not fit for surgery or patients not willing for surgery. These procedures reduce prolonged hospitalization and reduces economic burden to the patients.

Limitation(s):

This study had a few limitations. Firstly the study population was very small. Secondly the study was not randomized. The third limitation was that functional outcomes comparison was done with respect to two routes of steroid delivery which is neither disease specific nor anatomic lumbar level specific.

Conclusion

We conclude that both caudal epidural steroid injection and transforaminal epidural steroid injection provided significant relief of pain and increment of walking distance up to 3 months post injection and further significant longer duration of pain relief and increment of walking distance was observed in transforaminal route as compared to caudal epidural route.

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