International Orthopaedics (2019) 43:1883–1889
https://doi.org/10.1007/s00264-019-04350-w

ORIGINAL PAPER

Fluoroscopically guided caudal epidural steroid injections for axial low back pain associated with central disc protrusions: a prospective outcome study

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Received: 27 February 2019 / Accepted: 21 May 2019 / Published online: 5 June 2019

Abstract

Purpose To determine if axial low back pain (LBP) associated with central disc protrusions can be improved by caudal epidural steroid injections (ESIs).

Methods Adults with chronic (> 3 months) moderate-to-severe axial LBP with L4–5 and/or L5-S1 central disc protrusions were enrolled in this prospective study. Participants underwent caudal ESIs under standard-of-care practice. The numerical rating scale (NRS) pain score, modified North American Spine Society satisfaction, and Roland Morris Disability Questionnaire (RMDQ) were collected at one week, one month, three months, six months, and one year post-injection. Pre-injection magnetic resonance images were assessed by a musculoskeletal radiologist.

Results Sixty-eight participants (42 males, 26 females) were analyzed. There were statistically significant improvements in all outcome measures at all follow-up time points, with the exception of NRS best pain at six months. Clinically significant improvements in outcomes were observed at various time points: at three months and one year for current pain; at one week, one month, three months, six months, and one year for worst pain; and at one month and one year for RMDQ. The proportion of satisfied participants ranged from 57 to 69% throughout the study. No adverse events were observed.

Conclusions This study demonstrated significant improvements in pain and function following caudal ESIs in a cohort of axial LBP with associated central disc protrusions. Further studies, including the use of randomized controlled trials, are needed to determine the ideal subset of candidates for this treatment and to explore additional applications that caudal ESIs may have for chronic LBP.

Keywords Low back pain · Caudal epidural steroid injection · Axial · Central disc protrusion · Outcomes

Introduction

Low back pain (LBP) is a common cause of disability in individuals between the ages of 45 and 65 [1, 2]. Although it is believed that most episodes are self-limited and resolve without treatment, roughly 20% recur within six months [3]. In a specific subset of patients with LBP, the natural history may not be as benign as once thought, and repeated episodes can become chronic and debilitating. Distinguishing the precise origin of chronic LBP is often challenging. Pathology involving the intervertebral disc (IVD) has been implicated in 25–50% of chronic LBP cases and includes tears of the annulus fibrosis, herniation of disc material, and severe disruption of the disc architecture [4, 5]. Degenerative disc disease is characterized by loss of IVD homeostasis and is a prominent cause of LBP [6]. The posterior longitudinal ligament (PLL) has also been hypothesized as a pain generator in cases of axial LBP associated with lumbar disc protrusions [7].

The prognosis for resolution of discogenic LBP depends on the morphology of the herniation. Approximately 75–100% of broad-based disc protrusions, extrusions, and sequestrations resolve spontaneously, whereas only 3% of bulges and 38% of focal protrusions resolve on their own [8]. Accordingly, small and contained protrusions are more likely to have an

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insidious onset and may be more refractory to treatment with higher recurrence rates than extrusions [6].

Caudal epidural steroid injections (ESIs) have been shown to treat various LBP-causing pathologies, including degenerative disc disease, disc herniation with or without lumbar nerve root impingement and radicular symptoms, and lumbar spinal stenosis [9–12]. However, in a retrospective analysis of 98 patients who had axial LBP secondary to disc pathology at L4–5 and L5-S1 and underwent caudal ESIs, only 23% experienced > 50% pain relief for more than 1 year [13]. Cha et al. used magnetic resonance imaging (MRI) to determine possible outcome predictors of caudal ESIs for radicular pain caused by a herniated lumbar disc and found that a centrally located herniated disc was more common in responders. Other factors were not critical [14].

Although results from these investigations suggest that caudal ESIs may have therapeutic value for lumbar discogenic pain, there are limited studies on the clinical utility of this intervention for symptomatic central disc protrusions. Our theory is that the central and often ventral flow produced from the caudal technique may more precisely target the central disc protrusion and create a sustained therapeutic benefit. This study aimed to assess whether subjects with axial LBP and associated lumbar central disc protrusions would experience sustained improvements in pain and function after undergoing caudal ESIs.

Materials and methods

Study design and treatment

This prospective cohort study was approved by the Institutional Review Board and was conducted at a single outpatient academic spine center from April 2011 to November 2013. Written informed consent was obtained from all subjects.

Patients with a history of axial LBP were evaluated and enrolled if they had an L4–5 and/or L5-S1 central disc protrusion and recent MRI, did not respond to physical therapy and non-steroidal anti-inflammatory drugs, demonstrated moderate-to-severe pain (numerical rating scale [NRS] worst pain ≥ 5), and reported more sitting pain than standing pain. Exclusion criteria included prior surgery, spondylolisthesis, spondylolysis, presence of fractures, moderate-to-severe facet arthropathy, severe central canal stenosis, presence of vertebral body oedema, and radicular leg pain. Data were collected from medical records and included demographics, initial symptoms, previous treatments, imaging, diagnosis, and treatment information. Pre-injection questionnaires consisting of NRS pain scores and the Roland-Morris Disability Questionnaire (RMDQ) were obtained from each subject.

A musculoskeletal radiologist interpreted the pre-injection MRI for each study candidate and documented the type, size, location, and level(s) of disc protrusions. The Pfirmann, Pathria, and Modic scores were used to quantify the degree of disc degeneration, facet arthropathy, and endplate changes, respectively [15–17]. A candidate was excluded if there was no evidence of a central disc protrusion on MRI, the Pathria score was > 1, or the Pfirmann score was > IV (severe degenerative disease). An MRI of a typical study candidate is shown in Fig. 1.

In the interventional fluoroscopy suite, each patient underwent the injection in the prone position on the procedure table. The skin of the patient's back was sterile-prepped and draped before being anesthetized with 1% lidocaine. Under direct lateral fluoroscopic visualization, a 22-gauge, 2.5-in. spinal needle was then directed through the sacrococcygeal ligament and sacral hiatus into the sacral canal. After negative aspiration for cerebrospinal fluid or blood, contrast agent (Omnipaque 180, Amersham Health, Princeton, NJ) was instilled, and the epidurogram was obtained (Fig. 2). After central epidural flow was demonstrated on the epidurogram, a mixture containing 80 mg triamcinolone (Bristol-Myers Squibb, Princeton, NJ) and 6 cc of 1% lidocaine (Hospira, Inc., Lake Forest, IL) was instilled. At the conclusion of the procedure, the needle was withdrawn, sterile dressings were placed over the

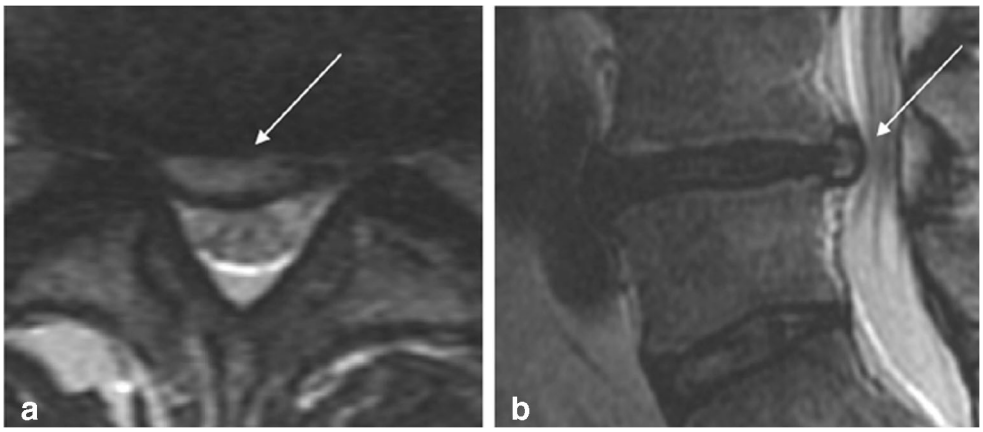

Fig. 1 Pre-injection magnetic resonance imaging of a typical study participant. **a** L4-L5 T2 axial image. **b** L4-L5 T2 sagittal image

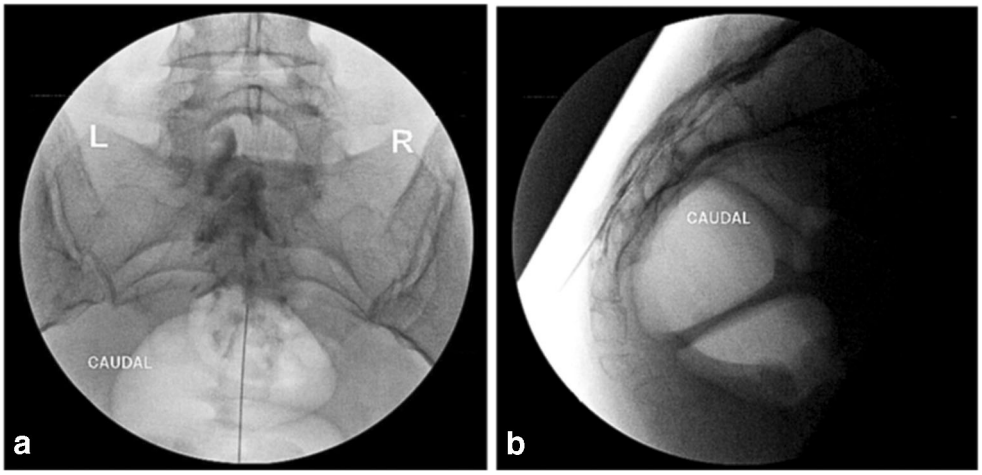

Fig. 2 Representative images of the caudal epidural steroid injection with contrast prior to treatment injection. **a** Anteroposterior view. **b** Lateral view

injection site, and the patient was transferred to the recovery area for observation.

Outcomes

Subjects were required to complete a questionnaire that included NRS pain, RMDQ, and the modified North American Spine Society (NASS) questionnaire for patient satisfaction at one week, one month, three months, six months, and one year post-injection. The NRS pain questionnaire asks participants to specify a numerical value from 0 to 10 on three different scales representing current, best, and worst pain. The minimum clinically important difference (MCID) for NRS pain is 2 points [18]. The RMDQ is designed for patients with spinal disorders and measures subjective perception of function and pain related to performing daily tasks and common manoeuvres [4]. The MCID for the RMDQ is 4 points [19].

Statistical analyses

A sample size of 50 subjects was determined necessary to observe a statistically significant change in NRS score with 80% power. Overall summary statistics are presented as means and standard deviations (SDs) for continuous variables and frequencies and percentages for categorical variables. Intention-to-treat analyses were performed for all outcomes. For the primary outcome (NRS pain), linear mixed models were used, and time effect was incorporated when analyzing longitudinal changes in these scores. For secondary outcomes, generalized estimating equations were used, and time effect was incorporated when analyzing longitudinal changes. Outcomes are presented as parameter estimates and standard errors. Significance was defined as $p < 0.05$. All analyses were conducted using SAS 9.4 (SAS, Cary, NC).

Results

Baseline characteristics

Eight-five study candidates were screened for eligibility. Seventeen subjects were excluded because no protrusion was detected on their MRIs. Therefore, the final cohort was composed of 68 patients. There were 42 males and 26 females, and the mean age was 41 years (SD 12).

Baseline MRI data are shown in Table 1. Seventeen (36%) patients had protrusions only at L5-S1, whereas 18 (38%) patients had central disc protrusions at multiple levels. The mean disc protrusion width was 15.8 mm (SD 5.1), and the mean depth was 3.4 mm (SD 1.1).

Outcomes

The cohort demonstrated statistically significant improvements in current pain, best pain, worst pain, and RMDQ scores at all follow-up time points ($p < 0.05$), with the

Table 1 Baseline magnetic resonance imaging data

	Other discs	L4-L5	L5-S1
Pfirmann Grade II	1 (13)	2 (8)	4 (14)
Pfirmann Grade III	7 (88)	5 (20)	10 (36)
Pfirmann Grade IV	0 (0)	18 (72)	12 (43)
Pfirmann Grade V	0 (0)	0 (0)	2 (7)
Pathria Grade 0	1 (20)	7 (28)	15 (58)
Pathria Grade I	4 (80)	12 (48)	8 (31)
Pathria Grade II	0 (0)	5 (20)	3 (12)
Pathria Grade III	0 (0)	1 (4)	0 (0)
Modic Type 0	6 (100)	13 (68)	12 (67)
Modic Type I	0 (0)	5 (26)	5 (28)
Modic Type II	0 (0)	1 (5)	1 (6)

Results are *n* (%)

exception of best pain scores at six months ($p = 0.07$). Furthermore, all outcome measures demonstrated statistically significant improvements over time throughout the follow-up period ($p < 0.001$). MCIDs were surpassed for current pain at three months and one year (3.35- and 2.48-point improvements, respectively); worst pain at one week, one month, three months, six months, and one year (2.50-, 3.41-, 2.65-, 2.62-, and 3.12-point improvements, respectively); and RMDQ at one month and one year (4.33- and 4.29-point improvements, respectively) (Table 2). The percentage of study participants that were satisfied with the injection ranged from 57 to 69% throughout the follow-up period (Fig. 3).

Multivariate regression models revealed no associations between age and outcomes. Males were significantly associated with lower worst pain scores ($p = 0.047$).

Post-injection care and safety

Within one year, six (8.8%) patients underwent a repeat caudal ESI. Eleven (16.2%) patients underwent transforaminal epidural steroid injections, intradiscal platelet-rich plasma injections, or facet injections. Subjects also sought additional care that included medications ($n = 22$; 32.4%), physical therapy ($n = 34$; 50%), and home exercises ($n = 52$; 76%). Two (2.9%) patients required surgery. No adverse effects of a progressive disc herniation, neurologic injury, or infection were reported.

Discussion

There is a void of published literature on the specific use of caudal ESIs for the management of axial LBP associated with

Table 2 Numerical rating scale pain and Roland-Morris Disability Questionnaire Outcomes

Outcome[a]	Time point	Estimate	Standard error	*P* value	Change from baseline
NRS current pain	Baseline	4.53	0.27	N/A	N/A
	1 week	2.82	0.28	< .0001	− 1.71
	1 month	2.69	0.34	< .0001	− 1.84
	3 months	1.18	0.38	< .0001	− 3.35*
	6 months	3.22	0.41	0.002	− 1.31
	1 year	2.05	0.48	< .0001	− 2.48*
	P value over time:			< .0001	
NRS best pain	Baseline	2.43	0.21	N/A	N/A
	1 week	1.57	0.20	< .0001	− 0.86
	1 month	1.59	0.25	0.001	− 0.84
	3 months	1.83	0.28	0.034	− 0.60
	6 months	1.86	0.31	0.067	− 0.57
	1 year	1.35	0.36	0.003	− 1.08
	P value over time:			0.0003	
NRS worst pain	Baseline	8.53	0.30	N/A	N/A
	1 week	6.03	0.33	< .0001	− 2.50*
	1 month	5.12	0.39	< .0001	− 3.41*
	3 months	5.88	0.43	< .0001	− 2.65*
	6 months	5.91	0.47	< .0001	− 2.62*
	1 year	5.41	0.54	< .0001	− 3.12*
	P value over time:			< .0001	
RMDQ	Baseline	8.53	0.63	N/A	N/A
	1 week	5.17	0.41	< .0001	− 3.36
	1 month	4.20	0.54	< .0001	− 4.33*
	3 months	4.84	0.65	< .0001	− 3.69
	6 months	5.06	0.74	< .0001	− 3.47
	1 year	4.24	0.88	< .0001	− 4.29*
	P value over time:			< .0001	

NRS numerical rating scale, *RMDQ* Roland-Morris Disability Questionnaire

*Change from baseline meets criteria for clinical significance (2 points for NRS pain, 4 points for RMDQ)

[a] Parameter estimates are shown

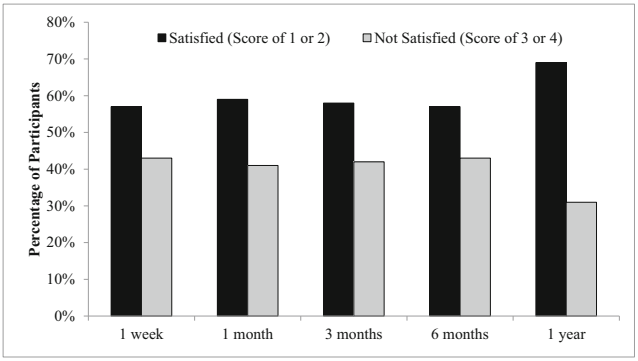

Fig. 3 Patient satisfaction over time. Satisfaction was assessed using the modified North American Spine Society questionnaire, which asked patients to select one of the following: (1) The procedure met my expectations; (2) the procedure improved my condition enough so that I would go through it again for the same outcome; (3) the procedure helped me but I would not go through it again for the same outcome; and (4) I am the same or worse compared to before the procedure. Scores of (1) and (2) were considered "satisfied," and scores of (3) and (4) were considered "not satisfied"

lumbar central disc protrusions without radiculopathy. Most studies do not stratify patients according to the type of disc pathology, which may be important if certain types respond better to ESIs than others. In our clinical experience, patients with axial LBP associated with isolated central protrusions of the L4–5 or L5-S1 disc seen on MRI are the best candidates for caudal ESIs. These patients generally require fewer additional interventional procedures compared to patients with axial LBP from other or multiple etiologies. Additionally, few studies have attempted to evaluate the relationship between patient-reported pain relief from ESIs for axial LBP and the type of disc pathology seen on MRI.

This study evaluated the potential clinical benefits of caudal ESIs for a specific subset of patients with axial LBP associated with L4–5 and/or L5-S1 central disc protrusions. In a cohort of 68 participants, we observed statistically significant improvements in pain and function at all time points up to 1 year, with the exception of NRS best pain score at six months. Long-term results show that most patients experienced statistically significant and clinically important improvements in pain and function over time, complemented by a satisfaction rate greater than 50% at all time points.

This study was rigid in its patient selection and included subjects with relatively homogeneous lumbar MRI results, predominantly moderate grades of disc degeneration, minimal facet joint degeneration, and minimal-to-no Modic endplate changes in most lumbar disc herniation levels. The positive outcomes suggest that patients with the MRI criteria outlined in the inclusion and exclusion criteria may be more likely to respond well to caudal ESIs. A future study with a more anatomically heterogeneous pool of patients may reveal more significant MRI differences.

Several studies have compared the effect of non-operative (e.g., ESIs) versus surgical treatment for LBP and have shown positive outcomes following both treatments. Greater improvement and less treatment failure following surgery have been reported [20, 21], although in patients with disc herniations, recurrences may also occur. Risk factors for recurrent disc herniations include lumbosacral transitional vertebrae, younger age, and hypermobility [20, 22]. Minimally invasive procedures, such as radiofrequency target disc decompression and nucleoplasty, have also been shown to reduce pain in patients with herniations [23]. Most of these studies focused on radicular pain.

The effect of ESIs specifically as a treatment for LBP has been well documented [24, 25]. However, many of these studies were limited by baseline differences between groups, inadequate sample sizes, the lack of validated outcome measures, and the lack of fluoroscopy to confirm the injectate location. Caudal ESIs have traditionally been described in the literature as an effective treatment for radicular pain [26]. Only a few studies have evaluated the role of caudal ESIs for lumbar discogenic back pain without radiculopathy. Using both clinical and radiological criteria, we identified a subset of patients with axial LBP associated with single- or two-level lumbar central disc protrusions who responded well to caudal ESIs. Caudal ESIs were shown to have the potential to provide long-term pain relief and functional improvement in properly selected patients.

Axial LBP associated with central lumbar disc protrusions may be caused by mechanical compression of an irritated region of the PLL proximal to the disc protrusion. Nakamura et al. elucidated the findings of a dense nerve network on the posterior portion of IVDs and PLL [27]. This rich area of nerve supply, inflammation, degeneration, or trauma to the posterior annulus or PLL may activate mechanosensitive or chemosensitive nociceptors in these tissues, resulting in axial LBP. Pain perceived from the posterior annulus and PLL may be transmitted from nociceptive sensory afferents and sympathetic fibres to the rami communicans through the posterior longitudinal ligament plexuses either directly or via the sinuvertebral nerve [28]. Delivery of medication to this region with a caudal ESI may be an effective means for treating axial LBP associated with central disc protrusions of the lower lumbar spine. The ideal flow pattern would be ventral and central along the PLL, reaching the level of the central disc protrusion. This type of flow pattern is unique to the caudal injection compared to other types of epidural injection techniques.

Although the underlying mechanism by which ESIs mediate LBP is not completely understood, it is postulated that the injection of anaesthetics and cortisone modulates the nociceptive input of afferent fibres in the pathologic areas of the disc and reduces inflammation by inhibiting the synthesis and/or release of pro-inflammatory mediators [28]. Additionally, anaesthetics and cortisone may reduce the nucleus pulposus-

induced early increase in vascular permeability in spinal nerve roots [29]. In cases of axial LBP, cortisone is thought to decrease inflammation and modulate pain in the region of the PLL [27]. Local anaesthetic injections alone have demonstrated pain relief through several potential mechanisms, including blockade of nociceptive discharges, sympathetic reflex arcs, and axonal transport processes [30]. A distinguishing feature of caudal ESIs may be its ability to deliver medication to the ventral and central epidural space along the PLL, in the region of suspected inflammation.

Limitations of this study include the lack of a control group. Future studies comparing the effect of caudal ESIs versus non-injection, conservative management (e.g., physical therapy, medications; "controls") on clinical outcomes in patients with axial LBP are warranted. In addition, post-injection care was not standardized and differed among patients. Because several physicians were involved, the availability of co-interventions likely varied. Patients also did not receive a standard injectate as part of their caudal ESI. Although considered off-label use for lumbosacral epidural injections, all study injections were done under fluoroscopic guidance and with digital subtraction angiography if warranted. Furthermore, the cost of injection was not covered by study funds, leading to potential bias from participants due to perceived investments in the caudal ESIs. Future studies may benefit from excluding patients with multiple disc protrusions in order to better understand the effects of the injection on axial LBP associated with a single protrusion at a single level.

The use of ESIs for LBP with or without radiculopathy is controversial, as studies differ in their findings both for efficacy and non-efficacy. In clinical practice, ESIs are used as part of the treatment algorithm for LBP and need to be assessed to determine who responds to ESIs so that clinicians can better understand where they can provide benefit to the patient. Our results suggest that a caudal ESI may have a long-term therapeutic benefit in a carefully selected subset of patients with axial LBP pain associated with central lumbar disc protrusions. Our results demonstrate significantly and clinically important improvements in pain and function that were sustained up to one year post-injection. Further studies are needed to more specifically determine the ideal patient subset for this treatment, as well as to explore pre- and post-treatment interventions that can lead to superior outcomes in patients with LBP.

Acknowledgments We thank Dr. Paul Cooke, Dr. Jennifer Solomon, Dr. Vincenzo Castellano, Dr. Matthew Diamond, Elizabeth LaSalle, and Kristen Santiago for their contributions to this study.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

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