



## Systematic review of the effectiveness of caudal epidural steroid injections in the treatment of chronic low back or radicular pain



Ameet S. Nagpal<sup>a,\*</sup>, To-Nhu Vu<sup>b</sup>, Benjamin Gill<sup>c</sup>, Aaron Conger<sup>d</sup>, Zachary L. McCormick<sup>d</sup>, Belinda Duszynski<sup>e</sup>, Brian T. Boies<sup>f</sup>

<sup>a</sup> Department of Orthopaedics & Physical Medicine, Medical University of South Carolina, Charleston, SC, USA

<sup>b</sup> Department of Anesthesiology & Perioperative Medicine, Penn State College of Medicine, Hershey, PA, USA

<sup>c</sup> Department of Physical Medicine and Rehabilitation, University of Missouri, Columbia, MO, USA

<sup>d</sup> Department of Physical Medicine & Rehabilitation, University of Utah School of Medicine, Salt Lake City, UT, USA

<sup>e</sup> Spine Intervention Society, Hinsdale, IL, USA

<sup>f</sup> Department of Anesthesiology, University of Texas Health Science Center at San Antonio, San Antonio, TX, USA

### ARTICLE INFO

#### Keywords:

Low back pain  
Radiculopathy  
Chronic post-surgical back pain  
Lumbar spinal stenosis  
Steroids  
Corticosteroids  
Analgesics  
Catheter  
Indwelling  
Caudal

### ABSTRACT

**Objective:** Determine the efficacy, effectiveness, and safety of fluoroscopically- or ultrasound-guided caudal epidural steroid injections (ESIs) with or without catheter placement for the treatment of chronic low back (CLBP), radicular pain, and/or chronic post-surgical back pain (CPSBP).

**Design:** Systematic review.

**Population:** Adults  $\geq 18$  years with CLBP, radicular pain, or CPSBP  $\geq 3$  months.

**Intervention:** Fluoroscopically- or ultrasound-guided caudal ESI with or without a catheter including epidural neuroplasty.

**Comparison:** Sham, placebo procedure, active standard care treatment, or none.

**Outcomes:** The primary outcome was the proportion of individuals with reduction of pain by  $\geq 50\%$ . Secondary outcomes included functional improvement, analgesic use, subsequent spinal surgery, healthcare utilization, and mean improvement in pain. Reported adverse events were also cataloged.

**Methods:** Four reviewers independently assessed publications before January 2, 2022 in PubMed, Ovid MEDLINE, and Scopus. Quality of evidence was evaluated using the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) framework.

**Results:** Of 364 records screened, 23 publications met inclusion criteria. The success rates for the primary outcome could only be extrapolated from one study. Another study used a composite improvement scale that included pain and functional outcomes. The reported success rates in these two studies ranged from 40 to 58% at three months, 25%–67% at six months, and 58%–61% at one year. Data on secondary outcomes were limited; however, rates of functional improvement as measured by mean improvement in Oswestry Disability Index (ODI) ranged from 2% to 55%.

**Conclusion:** There is moderate-quality evidence that caudal ESIs using an in-dwelling catheter for two days is an effective treatment for pain and dysfunction associated with disc herniation with radicular pain and for CPSBP at three, six, and 12 months. There is low-quality evidence supporting the effectiveness of other caudal ESI techniques for pain and dysfunction associated with central lumbar spinal stenosis with neurogenic claudication, discogenic CLBP, and CLBP without disc herniation or radiculitis.

### 1. Introduction

Epidural steroid injections (ESIs) are commonly utilized to treat

radicular pain syndromes throughout the spine. They have been used to treat lumbar radiculopathy since 1953 [1]. Additionally, they have been used in the treatment of spinal stenosis with neurogenic claudication or

\* Corresponding author. Department of Orthopaedics & Physical Medicine, Medical University of South Carolina, 96 Jonathan Lucas St. Suite 708, MSC 622, Charleston, SC, 29425, USA.

E-mail address: [nagpal@musc.edu](mailto:nagpal@musc.edu) (A.S. Nagpal).

<https://doi.org/10.1016/j.inpm.2022.100149>

Received 4 August 2022; Received in revised form 23 August 2022; Accepted 7 September 2022

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other neural involvement and axial chronic low back pain (CLBP), including chronic post-surgical back pain (CPSBP) [2–5]. Various methods allow for access of the epidural space. Depending on the spinal segmental origin of the pain, epidural access routes include interlaminar, transforaminal, and caudal approaches, with the last method used almost solely for lumbosacral pain [2,6–8]. The present systematic review focuses on the caudal route of epidural access and steroid administration with or without other adjunctive medications.

The caudal approach for ESI is often chosen due to perceived safety features associated with this route of administration. In addition, the point of entry to the caudal epidural space is almost always left intact following spine surgeries, which is often not the case with interlaminar access following posterior spinal decompression. Surgical hardware may also obscure transforaminal access in some individuals. The point of entry to the caudal epidural space is located below the vertebrae that are commonly decompressed and fused surgically, thereby reducing the incidence of dural puncture during epidural injection [6,9]. However, since this point of entry is distant from affected lumbar nerve roots and discs, interventionalists rely on higher volumes of injectate [6,7] or catheter use to ensure medication delivery to the targeted level(s) [10].

The caudal epidural approach also allows the safe use of particulate steroid, as this region of access contains venous plexus but no radiculomedullary arteries, similar to access of the interlaminar space, and in contrast to transforaminal access [11]. While the published evidence is mixed, use of particulate steroid for the treatment of radicular pain syndromes has been associated with a more durable treatment response in some studies [12–14]. As such, some physicians perceive an advantage of the caudal epidural approach with deposition of particulate steroid compared to transforaminal ESI with non-particulate steroid when an interlaminar route of access is not possible due to scarring of or obstruction of the dorsal epidural space in post-surgical patients.

In some cases, a catheter-based access method is used to deposit a low volume of epidural injectate with a relatively high concentration of steroid at the target level where lumbosacral pathology is present (compared to the high-volume injection needed to reach various lumbar levels using a caudal approach without a catheter) [15]. Typically, a “soft” epidural catheter is used with this method. In other cases, the catheter-based access method is paired with a technique initially described as a lysis of adhesions (LOA), adhesiolysis, or percutaneous epidural neuroplasty [16]. In this technique, the caudal epidural space is accessed via a percutaneous approach, and a stiff catheter is advanced to the targeted level(s) of disc herniation or scar tissue encroaching upon the affected nerve root(s) [16]. Typically, local anesthetic, steroid, and a substance used to “lyse” the adhesions, such as a 10% hypertonic saline or hyaluronidase, is injected through the catheter [17]. In addition to the injectate that provides chemical or enzymatic LOA, a balloon or other device may be used to provide mechanical LOA [18]. The catheter may be left in place for several days to allow repeated administration of medications (without steroid) prior to removal [16,17], though many studies also describe single or multiple injections in the same day followed by immediate removal of the catheter [19–24]. In this systematic review, all procedures in which steroids were injected via a caudal approach were included as our primary inclusion criterion to include single shot ESIs, ESIs with a catheter, and LOA procedures. For clarity, procedures involving use of a catheter where the intention was to chemically or mechanically “lyse” adhesions (LOA) or resolve a filling defect are hereafter termed “neuroplasty”.

A large volume of literature on caudal ESI and epidural neuroplasty has been published by a single common primary author [19–36], including several systematic reviews [37–39]. Regarding caudal ESI, evidence in one review was rated as “good” for disc herniation or radiculitis and “fair” for axial or discogenic pain without disc herniation, radiculitis, or facet joint pain; spinal stenosis; and CPSBP. Lumbar percutaneous adhesiolysis (neuroplasty) was rated at a “fair” level of evidence for CLBP and lower extremity pain secondary to post-surgery syndrome and spinal stenosis [38]. However, there is significant

concern for bias regarding the data and conclusions in these articles, including the reporting of primarily continuous data, poor description of intention-to-treat analysis, the authors' methods of addressing missing data, absent sensitivity analyses, and significant references to the authors' own work. Other reviewers noted similar concerns, stating “there is weak positive evidence that LOA is more effective for CPSBP and spinal stenosis, and that LOA is more effective than sham adhesiolysis and conservative management for lumbosacral radiculopathy” [40].

Until more conclusive studies are published, this systematic review was constructed to evaluate the quality of the existing evidence regarding the efficacy, effectiveness, and safety of caudal access and steroid administration in treating CLBP, radicular pain, and CPSBP. This systematic review was performed with the knowledge that studies would likely be found that utilized steroids in the caudal space but relied upon other injectates, catheter placement, etc. as the primary intervention being studied. For the purpose of this review, prior to evaluating the published literature, the authors elected to analyze any study that included steroid as an injectate in the caudal space, regardless of whether the steroid was the intended primary treatment of the original researchers.

### 1.1. Objectives and rationale

The objective of this systematic review was to identify and evaluate the quality of studies regarding the effectiveness and adverse events associated with procedures that introduce steroids into the caudal space.

## 2. Methods

### 2.1. Protocol and registration

This IRB-exempt study was registered on PROSPERO (ID: CRD42020192039, June 2020).

### 2.2. Eligibility criteria

#### 2.2.1. Population

Adults 18 years or older with CLBP, radicular pain, or CPSBP (often also referred to as “failed back surgery syndrome”) with symptoms for greater than 3 months. This criterion was changed from “symptoms for greater than 6 months” after the review was registered on PROSPERO during the literature search period based upon consensus from the research team. The intent was to capture the majority of the published literature, for which inclusion criteria more frequently required duration of symptoms of 3 months. Studies that did not report duration of pain or that reported duration of pain less than 3 months were omitted from the analysis.

#### 2.2.2. Intervention

Fluoroscopically- or ultrasound-guided caudal ESI with or without a catheter. For clarity, procedures involving use of catheter where the intention was to mechanically or chemically “lyse” adhesions (LOA) or resolve a filling defect are hereafter termed “neuroplasty”.

#### 2.2.3. Comparison

Sham, placebo procedure, active standard care treatment, or none.

#### 2.2.4. Outcome

The primary outcome of interest was the proportion of individuals with  $\geq 50\%$  pain reduction as measured by a validated scale such as the visual analog scale (VAS) or numeric rating scale (NRS). Secondary outcomes included the proportion of individuals with  $\geq 50\%$  functional improvement compared to baseline as measured by the Oswestry Disability Index (ODI), mean changes in ODI and NRS/VAS scores, analgesic medication use, patient satisfaction, subsequent lumbosacral spinal surgery, and utilization of healthcare related to the index

symptoms of interest. No restrictions were placed on the number of procedures performed. No restrictions were imposed regarding a minimum duration of outcome assessment. Outcomes were analyzed at two timeframes: between three and six months post-procedure and greater than six months post-procedure.

### 2.2.5. Studies

The present study included randomized controlled trials (RCTs), non-randomized comparative studies, and single group observational studies. Case reports, expert opinion, and non-English language manuscripts were excluded. No publication date restrictions were applied. For the purpose of this review, the authors analyzed *any* study that included steroid as an injectate in the caudal space, regardless of whether the steroid was the intended primary treatment of the original researchers.

### 2.3. Information sources and search

Clinical outcome studies on the effectiveness of caudal ESI for the treatment of CLBP or radicular pain were obtained by searching PubMed, Ovid MEDLINE, and Scopus, using the search terms “radiculopathy,” “failed back,” “chronic low back pain,” “disc degeneration,” “caudal,” “catheter,” and “adhesiolysis.” The searches were performed on February 1, 2022. Literature was also identified from the cited references of retrieved publications.

### 2.4. Study selection

Three authors (AN, BB, TV) independently assessed a subset of abstracts according to screening criteria. Two reviewers (BB, TV) assessed each abstract for eligibility. Discrepancies were resolved by a third reviewer (AN) not originally assigned to review those specific studies to reach a final decision regarding study inclusion. Subsequently, the full publications were independently reviewed by at least two authors (BB, TV) and assessed for inclusion. Discrepancies were again resolved by a third reviewer (AN).

Studies were included if they met the following criteria: 1) presentation of clinically relevant data on efficacy or effectiveness of caudal ESI for the treatment of CLBP or radicular pain *and* 2) presentation of valid information based on appropriate procedural technique, study methodology, and data analyses according to principles of EBM [41] or the ability to perform appropriate data analysis from raw published data.

### 2.5. Data items and collection

The following information was extracted from each study: 1) bibliographic details including year of publication and authors; 2) study design; 3) participant selection criteria; 4) technical description of the procedure; and 5) any relevant author disclosures or study funding. Additionally, outcome measures were recorded for pain reduction, functional improvement, patient satisfaction, analgesic medication use, lumbosacral spine surgery, healthcare resource utilization, and adverse events/complications.

### 2.6. Risk of bias and methodologic assessment

All reviewers have successfully achieved accreditation in the Spine Intervention Society's (SIS) Accreditation in Evidence-based Medicine Training Program. The program consists of two courses – Accreditation Course in Assessing Studies of Treatment (EBM I) and Accreditation Course in Assessing Studies of Diagnostic Tests and Strategies (EBM II). Each of these courses consist of 3–5 h of didactic presentations and require participation in a 2-h, small group discussion session with SIS EBM faculty. In order to attain accreditation, participants must pass all quizzes (six for EBM I and three for EBM 2), participate in the 2-h discussion sessions, and demonstrate competency on exams demonstrating understanding of statistical concepts and calculations and the ability to

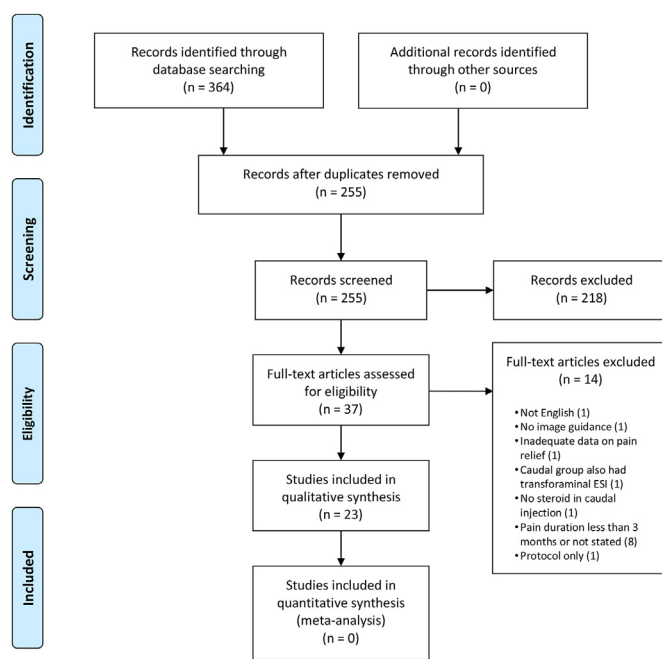


Fig. 1. Prisma 2009 flow diagram.

rigorously critique studies.

Reviewers evaluated all studies for various methodologic qualities known to impact study quality [41]. These considerations included a number of factors including; 1) selection of a patient sample representative of a realistic clinical population; 2) use of validated outcome measures; 3) <20% loss to follow-up (censoring); 4) use of controls for co-interventions; 5) authors' conflicts of interest; and 6) the validity of diagnostic criteria and assessment tools.

The body of evidence was evaluated using the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) system of appraisal to determine the quality of the evidence of the effectiveness of caudal ESI [42]. In the GRADE system, reviewers analyze the body of evidence pertaining to an intervention in domains including imprecision, risk of bias, inconsistency, indirectness, and publication bias. GRADE gives an initial quality rating based upon the existing evidence and allows for upgrading or downgrading of the overall evidence quality rating (e.g., upgrading for large magnitude of effect, or downgrading for risk of bias). Disagreements regarding GRADE evaluation were resolved by consensus decision among the reviewers.

### 2.7. Summary measures and synthesis of results

The primary outcome of interest was the proportion of “responders”, defined by  $\geq 50\%$  pain reduction from baseline at three months. Secondary outcomes included the proportion of individuals with  $\geq 50\%$  functional improvement compared to baseline as measured by the Oswestry Disability Index (ODI), mean changes in ODI and NRS/VAS scores, analgesic medication use, subsequent lumbosacral spinal surgery, and utilization of healthcare related to the index symptoms of interest. The GRADE system was applied to assess the quality of evidence related to the effectiveness of caudal ESI [43]. A meta-analysis was not performed due to significant heterogeneity of the study designs, populations studied, and primary and secondary outcomes.

## 3. Results

A total of 364 records were identified from the initial search. After abstract screening for relevant publications and removal of duplicates, 37 full text articles were assessed for eligibility and 23 were ultimately

**Table 1**  
Study characteristics.

Study	Study Design	Diagnosis/Question Addressed	Injectate/Catheter Duration	Follow-Up Interval
Akbas 2018 [46]	Pragmatic RCT	CPSBP To compare 3 adhesiolysis* approaches (caudal, S1 foraminal, L5-S1 transforaminal)	<i>Caudal:</i> ●catheter (procedure only) ●1500U hyaluronidase ●10 mL 1% lidocaine ●80 mg methylprednisolone	1 month 3 months 6 months
Chun-jing 2012 [47]	Pragmatic RCT	CPSBP To compare adhesiolysis vs caudal ESI	<i>Adhesiolysis:</i> ●catheter (procedure only) ●50–80 mL saline ●10 mg dexamethasone <i>Caudal ESI only:</i> ●no catheter ●10 mg dexamethasone	7 days 1 month 6 months
Gerdesmeyer 2013 [44]	Explanatory RCT	Radicular pain with disc herniation or CPSBP To compare neurolysis* vs placebo	<i>Neurolysis:</i> ●catheter (remained 2 days) ●10 mL 0.25% bupivacaine ●10 mL saline and 150U/mL hyaluronidase + each subsequent day (2 days): ●10 mL saline ●40 mg triamcinolone ●2 mL 0.25% bupivacaine <i>Placebo:</i> ●catheter in subcutaneous tissue ●10 mL saline each day	3 months 6 months 12 months
Gerdesmeyer 2021 [45]	Explanatory RCT	Radicular pain with disc herniation or CPSBP To compare neurolysis vs placebo	<i>Neurolysis:</i> ●catheter (remained 3 days) ●10 mL 0.25% bupivacaine ●10 mL saline and 150U/mL hyaluronidase + Post-neurolysis: ●10 mL saline ●40 mg triamcinolone ●2 mL 0.25% bupivacaine + each subsequent day (2 days): ●10 mL 0.25% bupivacaine ●10 mL saline ●2 mL 0.25% bupivacaine <i>Placebo:</i> ●catheter in subcutaneous tissue ●10 mL saline each day	12 months 120 months
Karm 2018 [18]	Pragmatic RCT	Central lumbar spinal stenosis with neurogenic claudication To compare inflatable catheter (ZiNeu) to balloon-less catheter (Racz) adhesiolysis	<i>ZiNeu:</i> ●catheter (remained 2 days) ●4 mL 1% lidocaine ●1500 IU hyaluronidase ●5 mg dexamethasone and 1% lidocaine ●4 mL 10% hypertonic saline After 2 days: ●5 mg dexamethasone ●2 mL 1% lidocaine ●4 mL 10% hypertonic saline <i>Racz:</i> ●catheter (remained 2 days) ●1500 IU hyaluronidase ●5 mg dexamethasone and 1% lidocaine ●4 mL 10% hypertonic saline After 2 days: ●5 mg dexamethasone ●2 mL 1% lidocaine ●4 mL 10% hypertonic saline	1 month 3 months 6 months
Manchikanti 2008 [25]	Pragmatic RCT	Radicular pain and disc herniation To compare caudal epidural injections with and without steroids	<i>Group 1:</i> ●10 mL 0.5% lidocaine ●2 mL 0.9% sodium chloride solution <i>Group 2:</i> ●9 mL 0.5% lidocaine ●1 mL 6 mg betamethasone or 40 mg methylprednisolone ●2 mL 0.9% sodium chloride solution	3 months 6 months 12 months
Manchikanti 2008 [26]	Pragmatic RCT	CLBP and radicular pain CPSBP To compare caudal epidural injections with and without steroids	<i>Group 1:</i> ●10 mL 0.5% lidocaine ●2 mL 0.9% sodium chloride solution <i>Group 2:</i>	3 months 6 months 12 months

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Table 1 (continued)

Study	Study Design	Diagnosis/Question Addressed	Injectate/Catheter Duration	Follow-Up Interval
			<ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•1 mL 6 mg betamethasone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	
Manchikanti 2008 [27]	Pragmatic RCT	CLBP and radicular pain Stenosis To compare caudal epidural injections with and without steroids	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•1 mL 6 mg betamethasone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	3 months 6 months 12 months
Manchikanti 2008 [28]	Pragmatic RCT	CLBP, discogenic pain without disc herniation or radiculitis To compare caudal epidural injections with and without steroids	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•1 mL 6 mg betamethasone or 40 mg methylprednisolone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	3 months 6 months 12 months
Manchikanti 2009 [24]	Pragmatic RCT	CLBP and radicular pain CPSBP To evaluate caudal epidural steroid versus epidural adhesiolysis	<i>Caudal ESI:</i> <ul style="list-style-type: none"> <li>•catheter (procedure only)</li> <li>•5 mL 2% lidocaine</li> <li>•6 mL saline</li> <li>•1 mL 6 mg betamethasone</li> <li>•1 mL normal saline</li> </ul> <i>Adhesiolysis:</i> <ul style="list-style-type: none"> <li>•Racz catheter (procedure only, adhesiolysis performed)</li> <li>•5 mL 2% lidocaine</li> <li>•6 mL 10% sodium chloride</li> <li>•1 mL 6 mg betamethasone</li> <li>•1 mL normal saline</li> </ul>	3 months 6 months 12 months
Manchikanti 2009 [20]	Pragmatic RCT	CLBP and radicular pain Stenosis To evaluate caudal epidural steroid versus epidural adhesiolysis	<i>Caudal ESI:</i> <ul style="list-style-type: none"> <li>•catheter (procedure only)</li> <li>•5 mL 2% lidocaine</li> <li>•6 mL saline</li> <li>•1 mL 6 mg betamethasone</li> <li>•1 mL normal saline</li> </ul> <i>Adhesiolysis:</i> <ul style="list-style-type: none"> <li>•Racz catheter (procedure only, adhesiolysis performed)</li> <li>•5 mL 2% lidocaine</li> <li>•6 mL 10% sodium chloride</li> <li>•1 mL 6 mg betamethasone</li> <li>•1 mL normal saline</li> </ul>	3 months 6 months 12 months
Manchikanti 2010 [29]	Pragmatic RCT	CLBP and radicular pain CPSBP To compare caudal epidural injections with and without steroids	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•6 mg betamethasone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	3 months 6 months 12 months
Manchikanti 2011 [30]	Pragmatic RCT	Radiculitis, disc herniation To compare caudal epidural injections with and without steroids	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•1 mL 6 mg betamethasone or 40 mg methylprednisolone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	3 months 6 months 12 months
Manchikanti 2011 [31]	Pragmatic RCT	CLBP without herniation or radiculitis To compare caudal epidural injections with and without steroids	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•1 mL 6 mg betamethasone or 40 mg methylprednisolone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	3 months 6 months 12 months
Manchikanti 2012 [32]	Pragmatic RCT	CLBP and radicular pain Stenosis To compare caudal epidural injections with and without steroids	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> </ul>	3 months 6 months 12 months 18 months 24 months

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Table 1 (continued)

Study	Study Design	Diagnosis/Question Addressed	Injectate/Catheter Duration	Follow-Up Interval
			<ul style="list-style-type: none"> <li>•1 mL 6 mg betamethasone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	
Manchikanti 2012 [33]	Pragmatic RCT	CLBP and radicular pain CPSBP To compare caudal epidural injections with and without steroids	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•1 mL 6 mg betamethasone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	3 months 6 months 12 months 18 months 24 months
Manchikanti 2012 [23]	Pragmatic RCT	CLBP and radicular pain CPSBP To compare caudal epidural steroid injections with epidural adhesiolysis	<i>Caudal ESI:</i> <ul style="list-style-type: none"> <li>•catheter (procedure only)</li> <li>•5 mL 2% lidocaine</li> <li>•6 mL 0.9% saline</li> <li>•1 mL 6 mg betamethasone</li> <li>•1 mL sodium chloride solution</li> <li>•6 mL 0.9% saline</li> </ul> <i>Neuroplasty:</i> <ul style="list-style-type: none"> <li>•Racz catheter (procedure only, adhesiolysis performed)</li> <li>•5 mL 2% lidocaine</li> <li>•6 mL 10% sodium chloride</li> <li>•1 mL 6 mg betamethasone</li> <li>•1 mL sodium chloride solution</li> </ul>	3 months 6 months 12 months 18 months 24 months
Manchikanti 2012 [34]	Pragmatic RCT	CLBP and radicular pain Stenosis To compare caudal epidural injections with and without steroids	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•1 mL 6 mg betamethasone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	3 months 6 months 12 months
Manchikanti 2012 [35]	Pragmatic RCT	Radiculitis, disc herniation To compare caudal epidural injections with and without steroids	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•1 mL 6 mg betamethasone or 40 mg methylprednisolone</li> <li>•2 mL 0.9% sodium chloride solution</li> </ul>	3 months 6 months 12 months 18 months 24 months
Manchikanti 2013 [19]	Pragmatic RCT	CLBP and radicular pain Stenosis To evaluate percutaneous adhesiolysis	<ul style="list-style-type: none"> <li>•Racz catheter (procedure only, adhesiolysis performed in all)</li> <li>•5 mL 2% lidocaine</li> <li>•6 mL 10% sodium chloride</li> <li>•1 mL 6 mg betamethasone</li> <li>•1 mL sodium chloride solution</li> </ul>	3 months 6 months 12 months 18 months 24 months
Manchikanti 2015 [36]	Retrospective comparison of results of 2 Pragmatic RCTs	CLBP, discogenic pain To compare caudal and lumbar interlaminar approaches of epidural injections with and without steroids	<i>Caudal, anesthetic only</i> <ul style="list-style-type: none"> <li>•10 mL 0.5% lidocaine</li> </ul> <i>Caudal, steroid</i> <ul style="list-style-type: none"> <li>•9 mL 0.5% lidocaine</li> <li>•1 mL "steroid"</li> </ul> <i>Lumbar interlaminar, anesthetic only</i> <ul style="list-style-type: none"> <li>•6 mL 0.5% lidocaine</li> </ul> <i>Lumbar interlaminar, steroid</i> <ul style="list-style-type: none"> <li>•5 mL 0.5% lidocaine</li> <li>•1 mL "steroid"</li> </ul>	3 months 6 months 12 months 18 months 24 months
Park 2013 [48]	Pragmatic RCT	Disc herniation or stenosis and radicular pain To compare ultrasound vs fluoroscopy guided caudal ESI	<i>Both groups:</i> <ul style="list-style-type: none"> <li>•1 mL 1% lidocaine</li> <li>•13 mL 0.5% lidocaine</li> <li>•2 mL 10 mg dexamethasone</li> </ul>	2 weeks 12 weeks
Yousef 2010 [49]	Pragmatic RCT	CPSBP To compare caudal ESI with and without hyaluronidase	<i>Group 1:</i> <ul style="list-style-type: none"> <li>•10 mL 0.25% bupivacaine</li> <li>•80 mg methylprednisolone</li> <li>•30 mL 3% hypertonic saline</li> </ul> <i>Group 2:</i> <ul style="list-style-type: none"> <li>•10 mL 0.25% bupivacaine</li> <li>•80 mg methylprednisolone</li> <li>•30 mL 3% hypertonic saline</li> <li>•1500 IU hyaluronidase</li> </ul>	6 weeks 3 months 6 months 12 months

RCT- "randomized controlled trial"; ESI- epidural steroid injection; CPSBP- chronic post-surgical back pain; CLBP- chronic low back pain. \*The term neuroplasty is used throughout the manuscript to describe procedures involving the use of a catheter where the intention was to chemically or mechanically "lyse" adhesions or resolve a filling defect. In this table the authors' preferred term is used.



included (Fig. 1). Studies that met the inclusion criteria consisted of two explanatory trials, 20 pragmatic trials, and one retrospective comparison of two pragmatic RCTs. Results were organized by study design and characteristics of individual studies and are summarized in Table 1. Categorical outcomes are reported in Table 2. Continuous outcomes for improvement in pain are reported in Table 3, and continuous outcomes for secondary outcomes are reported in Table 4. Adverse events are listed in Table 5. Because none of the included studies reported data on subsequent lumbosacral spinal surgery or utilization of healthcare related to the index symptoms of interest, these secondary outcomes are not represented in the tables.

### 3.1. Explanatory studies

One explanatory study that generated two articles met criteria for inclusion [44,45]. These two articles assess the efficacy of treatment for the same group of subjects; the 2013 manuscript presents three-month, six-month, and one-year follow-up data, and the 2021 manuscript presents one-year and 10-year follow-up data. Subjects with radiculopathy from disc herniation or CPSBP were randomized in a 1:1 ratio to receive either fluoroscopically-guided caudal epidural neuroplasty ( $n = 46$ ) (defined as a two-day in-dwelling catheter with solution injected as a slow bolus as described in Table 1) or a fluoroscopically-guided subcutaneous catheter placement with daily slow bolus of normal saline only ( $n = 44$ ). Subjects and assessing physicians were both blinded to group assignment. In a worst-case analysis, greater than 50% improvement in VAS was observed in 67% (95% Confidence Interval [CI]: 54%–81%), 70% (95% CI: 56%–83%), and 63% (95% CI: 49%–72%) of subjects at three, six, and 12 months, respectively. Greater than 50% improvement in ODI was reported by 57% (95% CI: 42%–71%), 67% (95% CI: 54%–81%), and 61% (95% CI: 47%–75%) of subjects at three, six, and 12 months, respectively, which was significantly higher than in the saline group [16% (95% CI: 5%–27%), 9% (95% CI: 1%–18%), and 20% (95% CI: 9%–32%) respectively]. These improvements in VAS and ODI were statistically significant and superior to placebo at all three timepoints ( $p < 0.05$ ). The mean VAS scores in the neuroplasty group improved from  $6.7 \pm 1.1$  at baseline to  $2.9 \pm 1.9$ ,  $1.4 \pm 0.9$ , and  $1.2 \pm 1.0$  at 3-, 6-, and 12-months post-procedure [44]. Thirty-eight percent and 31% of subjects were lost to follow up by one-year post-intervention in the neuroplasty and placebo groups, respectively.

Gerdesmeyer et al. additionally provided 10-year data from this study cohort [45]. At this time point, greater than 50% improvement in VAS was observed in 54% (95% CI: 40%–69%) of subjects who received the intervention and 34% (95% CI: 28%–48%) of subjects who received placebo. Also at this time point, greater than 50% improvement in ODI was reported by 54% (95% CI: 40%–69%) of subjects who received the intervention and 36% (95% CI: 28%–51%) of subjects who received placebo. In the neuroplasty group, mean VAS scores decreased from a baseline of  $6.7 \pm 1.1$  to  $1.2 \pm 1.1$  at one year and to  $1.5 \pm 1.4$  at 10 years. The differences in VAS and ODI score improvements between the two groups at the 10-year threshold were not statistically significant [45].

### 3.2. Pragmatic studies

One pragmatic study was identified that provided acceptable data on success rates for pain relief and functional improvement [18]. In this study, an inflatable catheter was compared to a balloon-less catheter introduced by caudal epidural access for subjects with central lumbar spinal stenosis with neurogenic claudication. Because both groups received steroid injections, data from each are reported. This study used a composite categorical score as the criterion for success (see Table 2 for the description of this composite score). In the balloon-less group, 40% (95% CI: 19%–61%), 40% (95% CI: 19%–61%), and 25% (95% CI: 6%–44%) of subjects met the composite categorical definition of treatment success at three, six, and 12 months, respectively. In the balloon group, 58% (95% CI: 39%–78%) met the composite categorical definition of

treatment success at all three time points.

None of the other pragmatic studies that met the established inclusion criteria of the present systematic review reported categorical data that could be effectively extrapolated. Fifteen studies reported categorical data and success rates, but these data could not be validly interpreted due to use of the “last data point carried forward” methodology, which represents a misutilization of the intention to treat analysis; allowance for repeat interventions within the study timeframe; unblinding of subjects during the study timeframe; absence of raw data to allow for independent calculations of success rates; and reporting results graphically without numerical representation in the text of the manuscript [19,20,23–35].

Improvement in pain using continuous data was reported in 21 pragmatic studies [18–20,23–36,46–49]. Various time points were evaluated in these studies. The range of mean improvement in pain scores for three- to six-month post-procedure time points in these studies was 12%–79% (Table 3). While differences exist between how individual studies defined specific diagnoses, and several studies combined diagnoses without separating them for interpretation, there were several identifiable diagnoses that could be grouped for interpretation of continuous data. These included CPSBP, disc herniation with radicular pain, central stenosis with radicular pain, and low back pain without disc herniation or radiculitis. For CPSBP, the range of mean improvement in pain scores at three- to six-months after caudal ESI was 12–79% (Table 3). For disc herniation with radicular pain, the range of mean improvement in pain score at three- to six-month time points after caudal ESI was 57–79% (Table 3). For central stenosis with radicular pain, the range of mean improvement in pain score at three- to six-month time points after caudal ESI was 13–61% (Table 3). For non-radicular LBP, the range of mean improvement in pain scores at three- to six-month time points after caudal ESI was 48–55% (Table 3).

Seventeen studies reported improvement in mean pain score at an endpoint greater than six months post-procedure [19,20,23–36,49]. Endpoints included 12 months, 18 months, and 24 months post-procedure. The range of mean improvement in pain score post-procedure in these studies at these endpoints was 45–56% (Table 3). As above, identifiable diagnoses that could be grouped for interpretation of continuous data included CPSBP, disc herniation with radicular pain, central stenosis with radicular pain, and non-radicular LBP. The range of mean improvement in pain scores after six months following caudal ESI was 46–56% for CPSBP, 54–56% for disc herniation with radicular pain, 38–51% for central stenosis with radicular pain, and 51–53% for non-radicular LBP (Table 3).

Nineteen pragmatic studies evaluated functional improvement (Table 4) [18–20,23–36,46,48]. All 19 described a mean improvement in ODI. The range of improvement in ODI at three- to six-month time points post-procedure was 14–54%. The range of mean improvement in ODI for the endpoints beyond six months post-procedure was 17–53%.

Fifteen studies assessed change in opioid consumption (see Table 4) [19,20,23–32,34,35,47]. All 15 studies described a mean reduction in morphine equivalents (MME). The range of improvement in reduction of MME at three- to six-month time points post-procedure was 14–51%. The range of improvement in reduction of MME for greater than six-month post-procedure endpoints was 15–41%.

### 3.3. Adverse events

Adverse events data were collected and assessed from each of the included studies. No serious adverse events were identified in any of the studies. Subarachnoid needle or catheter placement was identified in 9% (14/155) [95% CI: 5–14%] of subjects treated with epidural neuroplasty across three studies [19,20,23], while subdural needle placement was noted in 5% (1/20) (95% CI: 0–15%) of subjects treated with a caudal ESI in one study [46]. No other identifiable patterns of adverse events were noted (Table 5).

**Table 2**  
Categorical data on pain and functional improvement.

Study	Determinant of Successful Treatment - Pain	Categorical Pain Improvement at Each Interval	Determinant of Successful Treatment - Function	Categorical Functional Improvement at Each Interval
Gerdesmeyer 2013 [44]	≥50% improvement VAS	Neurolysis* (n = 46) 3 m: 31/46, 67% (95% CI: 54–81%) 6 m: 32/46, 70% (95%CI: 56–83%) 12 m: 29/46, 63% (95%CI: 49–72%)	≥50% improvement ODI	Neurolysis (n = 46) 3 m: 26/46, 57% (95% CI: 42–71%) 6 m: 31/46, 67% (95% CI: 54–81%) 12 m: 28/46, 61% (95%CI: 47–75%)
Gerdesmeyer 2021 [45]	≥50% improvement VAS	Neurolysis (n = 46) 12 m: 29/46, 63% (95%CI: 49–77%) 120 m: 25/46, 54% (95%CI: 40–69%)	≥50% improvement ODI	Neurolysis (n = 46) 12 m: 28/46, 61% (95%CI: 47–75%) 120 m: 25/46, 54% (95%CI: 40–69%)
Karm 2018 [18]	(1) ≥ 50% (or ≥ 4-point) reduction from baseline leg or lower back NRS-11, and no increase from baseline ODI and MQS, and ≥4 points on the GPES scale, or (2) ≥ 30% (or ≥ 2-point) reduction from baseline NRS with any one of the following criteria: simultaneous ≥30% (or ≥ 10-point) reduction in ODI from baseline, ≥ 6 points on the GPES scale, or ≥ 25% reduction in MQS from baseline	LOA * Racz (n = 20) 1 m: 8/20, 40% (95% CI: 19%–61%) 3 m: 8/20, 40% (95% CI: 19%–61%) 6 m: 5/20, 25% (95% CI: 6%–44%) LOA Zineu (n = 24) 3 m: 14/24, 58% (95%CI: 39%–78%) 6 m: 14/24, 58% (95%CI: 39%–78%) 12 m: 14/24, 58% (95%CI: 39%–78%)	(1) ≥ 50% (or ≥ 4-point) reduction from baseline leg or lower back NRS-11, and no increase from baseline ODI and MQS, and ≥4 points on the GPES scale, or (2) ≥ 30% (or ≥ 2-point) reduction from baseline NRS with any one of the following criteria: simultaneous ≥30% (or ≥ 10-point) reduction in ODI from baseline, ≥ 6 points on the GPES scale, or ≥ 25% reduction in MQS from baseline  ≥30% Improvement in ODI	LOA Racz (n = 20) 1 m: 8/20, 40% (95% CI: 19%–61%) 3 m: 8/20, 40% (95% CI: 19%–61%) 6 m: 5/20, 25% (95% CI: 6%–44%) LOA ZiNeu (n = 24) 3 m: 14/24, 58% (95% CI: 39%–78%) 6 m: 14/24, 58% (95% CI: 39%–78%) 12 m: 14/24, 58% (95%CI: 39%–78%)  LOA Racz (n = 20) 1 m: 6/20, 30% (95% CI: 10%–50%) 3 m: 7/20, 35% (95% CI: 14%–56%) 6 m: 4/20, 20% (95% CI: 2%–38%) LOA ZiNeu (n = 24) 1 m: 13/24, 54% (95% CI: 34%–74%) 3 m: 15/24, 63% (95% CI: 43%–82%) 6 m: 13/24, 54% (95% CI: 34%–74%)

VAS- Visual Analog Scale; ODI- Oswestry Disability Index; NRS- Numeric Rating Scale; 95%CI: 95% Confidence Interval; MQS- Medication Quantification Scale; GPES- Global Perceived Effect Scale; LOA- Lysis of adhesions; \*The term neuroplasty is used throughout the manuscript to describe procedures involving the use of a catheter where the intention was to chemically or mechanically “lyse” adhesions or resolve a filling defect. In this table the authors’ preferred term is used.

**3.4. GRADE assessment of the evidence**

There is only one explanatory randomized controlled trial with valid, interpretable success rates published on the use of caudal ESIs, and data are reported in two separate articles from this trial [44,45]. The second of these studies reports 10-year follow-up data that are unlikely to be related to the original intervention. There is a wide variety of heterogeneity of study design, injectate, and diagnosis inclusions for the remaining pragmatic studies. Gerdesmeyer et al. performed epidural neuroplasty by placing a catheter in the caudal epidural space for two days with a specific injectate (Table 1). With RCT evidence available for this particular form of intervention, the resulting body of evidence is initially assigned a “high” GRADE quality of evidence rating. However, this body of evidence is downgraded due to imprecision of results, which represents a serious risk of bias. This is based upon a small sample of available explanatory data that have not been replicated, leading to large confidence intervals and uncertainty regarding the findings. Therefore, the GRADE level for the quality of evidence for epidural neuroplasty to improve pain and function associated with radiculopathy from disc herniation or CPSBP is moderate at three, six, and 12 months. The quality of evidence for the use of caudal ESI for the treatment of pain and dysfunction associated with radiculopathy in disc herniation or CPSBP

using any technique other than the epidural neuroplasty technique described by Gerdesmeyer et al. is low. While there are pragmatic RCTs, which confer an initial GRADE assignment of high quality to the evidence, the quality of the body of evidence is downgraded because the studies are biased by imprecise effect size (small sample sizes and unreliable categorical and continuous data), indirectness (substantial differences in the methodology of caudal ESI technique as well as substantial population differences), and inconsistency in results (large differences in effect between studies).

The GRADE assessment for the use of caudal ESI for pain and dysfunction associated with the following diagnoses at all included time points is low: central lumbar spinal stenosis with neurogenic claudication, discogenic CLBP, and CLBP without disc herniation/radiculitis. While there are pragmatic RCTs, which confer an initial GRADE assignment of high quality to the evidence, the quality of the body of evidence is downgraded because the studies are biased by imprecise effect size, indirectness, and inconsistency.

**4. Discussion**

The primary focus of the present review was to rigorously and comprehensively analyze the published literature on the efficacy and



**Table 3**  
Continuous data - pain relief.

Study	Follow-Up Interval	Pain Outcome Measure	% Mean Improvement in Remaining Subjects at Each Interval	Diagnosis/Question Addressed
Akbas 2018 [46]	1 month 3 months 6 months	VAS	<i>Caudal</i> 69% 59% 53% <i>S1 transforaminal</i> 71% 64% 56% <i>L5-S1 transforaminal</i> 67% 56% 51%	CPSBP To compare 3 adhesiolysis* approaches (caudal, S1 transforaminal, L5-S1 transforaminal)
Chun-jing 2012 [47]	7 days 1 month 6 months	VAS	<i>Adhesiolysis</i> 50% 49% 47% <i>Caudal ESI only</i> 22% 15% 12%	CPSBP To compare adhesiolysis vs caudal ESI
Gerdesmeyer 2013 [44]	3 months 6 months 12 months	VAS	<i>Neurolysis*</i> 57% 79% 82%	Radicular pain w/disc herniation or CPSBP To compare neurolysis* vs placebo
Gerdesmeyer 2021 [45]	12 months 120 months	VAS	<i>Neurolysis</i> 82% 78%	Radicular pain w/disc herniation or CPSBP To compare neurolysis vs placebo
Karm 2018 [18]	1 month 3 months 6 months	NRS leg NRS back	<i>LOA Racz (NRS leg)</i> 34% 25% 13% <i>LOA Racz (NRS back)</i> 34% 30% 22% <i>LOA ZiNeu (NRS leg)</i> 27% 40% 47% <i>LOA ZiNeu (NRS back)</i> 29% 38% 46%	Central lumbar spinal stenosis w/neurogenic claudication To compare inflatable catheter (ZiNeu) to balloon-less catheter (Racz) LOA
Manchikanti 2008 [25]	3 months 6 months 12 months	NRS	<i>Caudal, No Steroid</i> 53% 55% 54% <i>Caudal ESI</i> 57% 56% 56%	Radicular pain and disc herniation To compare caudal epidural injections with and without steroids
Manchikanti 2008 [26]	3 months 6 months 12 months	NRS	<i>Caudal, No Steroid</i> 53% 55% 54% <i>Caudal ESI</i> 57% 56% 56%	Chronic LBP and radicular pain CPSBP To compare caudal epidural injections with and without steroids
Manchikanti 2008 [27]	3 months 6 months 12 months	NRS	<i>Caudal, No Steroid</i> 48% 51% 53% <i>Caudal ESI</i> 44% 45% 45%	CLBP and radicular pain Stenosis To compare caudal epidural injections with and without steroids

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Table 3 (continued)

Study	Follow-Up Interval	Pain Outcome Measure	% Mean Improvement in Remaining Subjects at Each Interval	Diagnosis/Question Addressed
Manchikanti 2008 [28]	3 months	NRS	<i>Caudal, No Steroid</i>	CLBP, discogenic pain without disc herniation or radiculitis To compare caudal epidural injections with and without steroids
	6 months		53%	
	12 months		54%	
			53%	
			<i>Caudal ESI</i>	
			53%	
			52%	
			51%	
Manchikanti 2009 [24]	3 months	NRS	<i>Caudal ESI</i>	Chronic LBP and radicular pain CPSBP To evaluate caudal epidural steroid versus epidural adhesiolysis
	6 months		38%	
	12 months		27%	
			23%	
			<i>Adhesiolysis</i>	
			58%	
			54%	
			51%	
Manchikanti 2009 [20]	3 months	NRS	<i>Caudal ESI</i>	CLBP and radicular pain Stenosis To evaluate caudal epidural steroid versus epidural adhesiolysis
	6 months		33%	
	12 months		25%	
			23%	
			<i>Adhesiolysis</i>	
			54%	
			51%	
			50%	
Manchikanti 2010 [29]	3 months	NRS	<i>Caudal, No Steroid</i>	CLBP and radicular pain CPSBP To compare caudal epidural injections with and without steroids
	6 months		47%	
	12 months		44%	
			43%	
			<i>Caudal ESI</i>	
			47%	
			47%	
			46%	
Manchikanti 2011 [30]	3 months	NRS	<i>Caudal, No Steroid</i>	Radiculitis, disc herniation To compare caudal epidural injections with and without steroids
	6 months		49%	
	12 months		52%	
			49%	
			<i>Caudal ESI</i>	
			56%	
			55%	
			55%	
Manchikanti 2011 [31]	3 months	NRS	<i>Caudal, No Steroid</i>	CLBP without herniation or radiculitis To compare caudal epidural injections with and without steroids
	6 months		48%	
	12 months		49%	
			46%	
			<i>Caudal ESI</i>	
			54%	
			53%	
			52%	
Manchikanti 2012 [32]	3 months	NRS	<i>Caudal, No Steroid</i>	CLBP and radicular pain Stenosis To compare caudal epidural injections with and without steroids
	6 months		48%	
	12 months		48%	
	18 months		44%	
	24 months		43%	
	42%			
	<i>Caudal ESI</i>		46%	
			45%	
			43%	
			42%	
			38%	
Manchikanti 2012 [33]	3 months	NRS	<i>Caudal, No Steroid</i>	CLBP and radicular pain CPSBP To compare caudal epidural injections with and without steroids
	6 months		46%	
	12 months		45%	
	18 months		42%	
	24 months		41%	
	44%			
	<i>Caudal ESI</i>		47%	
			47%	
			46%	
			47%	
			46%	

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Table 3 (continued)

Study	Follow-Up Interval	Pain Outcome Measure	% Mean Improvement in Remaining Subjects at Each Interval	Diagnosis/Question Addressed	
Manchikanti 2012 [23]	3 months	NRS	<i>Caudal ESI</i>	CLBP and radicular pain CPSBP To compare caudal epidural steroid injections with epidural adhesiolysis	
	6 months		38%		
	12 months		27%		
	18 months		23%		
	24 months		23%		
			22%		
		<i>Adhesiolysis</i>	58%		
			54%		
			51%		
			56%		
			56%		
Manchikanti 2012 [34]	3 months	NRS	<i>Caudal, No Steroid</i>	CLBP and radicular pain Stenosis  To compare caudal epidural injections with and without steroids	
	6 months		48%		
	12 months		48%		
			44%		
			<i>Caudal ESI</i>		46%
					45%
		43%			
Manchikanti 2012 [35]	3 months	NRS	<i>Caudal, No Steroid</i>	Radiculitis, disc herniation To compare caudal epidural injections with and without steroids	
	6 months		49%		
	12 months		52%		
	18 months		49%		
	24 months		49%		
			48%		
		<i>Caudal ESI</i>	56%		
			55%		
			55%		
			55%		
			54%		
Manchikanti 2013 [19]	3 months	NRS	<i>Adhesiolysis</i>	CLBP and radicular pain Stenosis To evaluate epidural adhesiolysis	
	6 months		55%		
	12 months		53%		
	18 months		50%		
	24 months		51%		
			48%		
Manchikanti 2015 [36]	3 months	NRS	<i>Caudal, No Steroid</i>	CLBP, discogenic pain To compare caudal and lumbar interlaminar approaches of epidural injections with and without steroids	
	6 months		51%		
	12 months		51%		
	18 months		49%		
	24 months		48%		
			48%		
		<i>Caudal ESI</i>	55%		
			53%		
			53%		
			50%		
			53%		
Park 2013 [48]	2 weeks	VAS	<i>Ultrasound</i>	Disc herniation or stenosis and radicular pain To compare ultrasound vs fluoroscopy guided caudal ESI	
	12 weeks		51%		
			61%		
			<i>Fluoroscopy</i>		51%
					59%
Yousef 2010 [49]	6 weeks	Verbal Scale (0–4, 4 “extremely severe”)	<i>Caudal ESI</i>	CPSBP To compare caudal ESI with and without hyaluronidase	
	3 months		54%		
	6 months		49%		
	12 months		28%		
			15%		
			<i>Caudal ESI + Hyaluronidase</i>		55%
		52%			
		56%			
		50%			

ESI- Epidural Steroid Injection; CLBP- Chronic low back pain; CPSBP- Chronic post-surgical back pain; LOA- Lysis of adhesions; VAS- Visual Analog Scale; NRS- Numeric Rating Scale; \*The term neuroplasty is used throughout the manuscript to describe procedures involving the use of a catheter where the intention was to chemically or mechanically “lyse” adhesions or resolve a filling defect. In this table the authors' preferred term is used.

**Table 4**  
Continuous data - functional improvement and analgesic use.

Study	Follow-Up Interval	Functional Outcome Measure	% Mean Improvement in Remaining Subjects at Each Interval	Analgesic Improvement Outcome Measure	% Mean Improvement in Remaining Subjects at Each Interval					
Akbas 2018 [46]	1 month 3 months 6 months	ODI	<i>Caudal</i>							
			52%							
			46%							
			44%							
			<i>S1 Transforaminal</i>							
			71%							
			64%							
			56%							
			<i>L5-S1 Transforaminal</i>							
			67%							
Chun-jing 2012 [47]	7 days 1 month 6 months			MME reduction	<i>Adhesiolysis:</i>					
					50%					
					50%					
					51%					
					<i>Caudal ESI only:</i>					
					33%					
					21%					
					20%					
					Gerdesmeyer 2013 [44]	3 months 6 months 12 months	ODI	<i>Neurolysis</i>		
								52%		
78%										
83%										
Gerdesmeyer 2021 [45]	12 months 120 months	ODI	<i>Neurolysis</i>							
			83%							
			79%							
Karm 2018 [18]	1 month 3 months 6 months	ODI	<i>Racz</i>							
			21%							
			23%							
			14%							
			<i>ZiNeu</i>							
			29%							
33%										
42%										
Manchikanti 2008 [25]	3 months 6 months 12 months	ODI	<i>Caudal, No Steroid</i>	MME reduction	<i>Caudal, No Steroid</i>					
			46%		41%					
			50%		41%					
			51%		41%					
			<i>Caudal ESI</i>		<i>Caudal ESI</i>					
			52%		40%					
			53%		41%					
			56%		40%					
			Manchikanti 2008 [26]		3 months 6 months 12 months	ODI	<i>Caudal, No Steroid</i>	MME reduction	<i>Caudal, No Steroid</i>	
							45%		31%	
44%	16%									
45%	30%									
<i>Caudal ESI</i>	<i>Caudal ESI</i>									
43%	32%									
44%	33%									
42%	34%									
Manchikanti 2008 [27]	3 months 6 months 12 months	ODI		<i>Caudal, No Steroid</i>			MME reduction		<i>Caudal, No Steroid</i>	
				42%					22%	
			46%	24%						
			50%	24%						
			<i>CESI</i>	<i>Caudal ESI</i>						
			37%	36%						
			41%	38%						
			39%	38%						
			Manchikanti 2008 [28]	3 months 6 months 12 months	ODI	<i>Caudal, No Steroid</i>		MME reduction	<i>Caudal, No Steroid</i>	
						49%			25%	
51%	25%									
51%	25%									
<i>Caudal ESI</i>	<i>Caudal ESI</i>									
49%	25%									
51%	17%									
51%	24%									

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Table 4 (continued)

Study	Follow-Up Interval	Functional Outcome Measure	% Mean Improvement in Remaining Subjects at Each Interval	Analgesic Improvement Outcome Measure	% Mean Improvement in Remaining Subjects at Each Interval
Manchikanti 2009 [24]	3 months	ODI	<i>Caudal ESI</i>	MME reduction	<i>Caudal ESI</i>
	6 months		29%		2%
	12 months		22%		15%
			19%		2%
			<i>Adhesiolysis</i>		34%
		51%		23%	
		51%		36%	
		49%			
Manchikanti 2009 [20]	3 months	ODI	<i>Caudal ESI</i>	MME reduction	<i>Caudal ESI</i>
	6 months		23%		17%
	12 months		17%		17%
			16%		17%
			<i>Adhesiolysis</i>		16%
		49%		16%	
		48%		16%	
		49%		16%	
Manchikanti 2010 [29]	3 months	ODI	<i>Caudal, No Steroid</i>	MME reduction	<i>Caudal, No Steroid</i>
	6 months		42%		18%
	12 months		42%		22%
			42%		22%
			<i>Caudal ESI</i>		17%
		44%		17%	
		43%		15%	
Manchikanti 2011 [30]	3 months	ODI	<i>Caudal, No Steroid</i>	MME reduction	<i>Caudal, No Steroid</i>
	6 months		43%		12%
	12 months		47%		13%
			47%		12%
			<i>Caudal ESI</i>		33%
		51%		31%	
		53%		31%	
Manchikanti 2011 [31]	3 months	ODI	<i>Caudal, No Steroid</i>	MME reduction	<i>Caudal, No Steroid</i>
	6 months		42%		17%
	12 months		43%		9%
			46%		9%
			<i>Caudal ESI</i>		17%
		49%		14%	
		50%		17%	
		49%			
Manchikanti 2012 [32]	3 months	ODI	<i>Caudal, No Steroid</i>	MME reduction	<i>Caudal, No Steroid</i>
	6 months		42%		27%
	12 months		42%		25%
	18 months		41%		21%
	24 months		41%		22%
	41%	22%			
	<i>Caudal ESI</i>	33%			
		40%		32%	
		40%		32%	
		41%		32%	
		37%		34%	
Manchikanti 2012 [33]	3 months	ODI	<i>Caudal, No Steroid</i>		
	6 months		42%		
	12 months		42%		
	18 months		42%		
	24 months		41%		
	41%				
	<i>Caudal ESI</i>	42%			
		44%			
		43%			
		43%			
		43%			

(continued on next page)



Table 4 (continued)

Study	Follow-Up Interval	Functional Outcome Measure	% Mean Improvement in Remaining Subjects at Each Interval	Analgesic Improvement Outcome Measure	% Mean Improvement in Remaining Subjects at Each Interval
Manchikanti 2012 [23]	3 months	ODI	<i>Caudal ESI</i>	MME reduction	<i>Caudal ESI</i>
	6 months		29%		2%
	12 months		22%		2%
	18 months		19%		2%
	24 months		19%		2%
			19%		2%
			<i>Adhesiolysis</i>		<i>Adhesiolysis</i>
			51%		23%
			51%		24%
			49%		21%
			53%		23%
	55%	23%			
Manchikanti 2012 [34]	3 months	ODI	<i>Caudal, No Steroid</i>	MME reduction	<i>Caudal, No Steroid</i>
	6 months		42%		28%
	12 months		42%		25%
			41%		21%
			<i>Caudal ESI</i>		<i>Caudal ESI</i>
			40%		33%
			40%		32%
	40%	32%			
Manchikanti 2012 [35]	3 months	ODI	<i>Caudal, No Steroid</i>	MME reduction	<i>Caudal, No Steroid</i>
	6 months		43%		37%
	12 months		47%		36%
	18 months		47%		37%
	24 months		47%		37%
			47%		37%
			<i>Caudal ESI</i>		<i>Caudal ESI</i>
			51%		33%
			51%		31%
			53%		31%
			53%		31%
	52%	31%			
Manchikanti 2013 [19]	3 months	ODI	<i>Adhesiolysis*</i>	MME reduction	<i>Adhesiolysis</i>
	6 months		51%		31%
	12 months		50%		31%
	18 months		49%		27%
	24 months		50%		29%
			51%		27%
Manchikanti 2015 [36]	3 months	ODI	<i>Caudal, No Steroid</i>		
	6 months		46%		
	12 months		46%		
	18 months		46%		
	24 months		45%		
			45%		
			<i>Caudal ESI</i>		
			51%		
			50%		
			50%		
			50%		
	51%				
Park 2013 [48]	2 weeks	ODI	<i>Ultrasound Caudal ESI</i>		
	12 weeks		35%		
			43%		
			<i>Fluoroscopic Caudal ESI</i>		
			41%		
			44%		

ESI- Epidural Steroid Injection; ODI-Oswestry Disability Index; MME- Morphine Milligram Equivalent; \*The term neuroplasty is used throughout the manuscript to describe procedures involving the use of a catheter where the intention was to chemically or mechanically “lyse” adhesions or resolve a filling defect. In this table the authors' preferred term is used.

effectiveness of caudal ESI for the treatment of chronic back and/or lower extremity pain due to a variety of diagnoses. Relevant studies were selected for inclusion using criteria from established guidelines [41,50].

The recommendations for the importance of categorical data analyses have been well-documented in the medical literature. A panel of leading authorities in the field of Pain Medicine published recommendations known as “Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials” (IMMPACT) guidelines. These authors emphasized the importance of reporting categorical data analysis (Anchor-Based Methods) over group (mean) data analysis (Distribution-Based Methods)

[50]. While group data may provide a statistical indication that a treatment is effective, it does not provide any information on the proportion of patients in which the treatment is effective, the number of patients for which it is effective, or the magnitude of effectiveness in a particular patient [51].

Trends emerge when assessing the level of evidence in accordance with GRADE. In this review, the authors encountered both explanatory and pragmatic RCTs. There are many studies in which caudal access is obtained and steroids are injected. There is a finite number of diagnoses for which caudal ESIs are generally used. Each of these diagnoses is

**Table 5**  
Adverse events.

Study	Adverse Events
Akbas 2018 [46]	No serious adverse events L5-S1 TFESI: 1 headache, 1 post-operative paresthesia S1 TFESI: 1 subdural contrast spread, 1 hypotension, 1 dural puncture Caudal ESI: 1 subdural contrast spread, 1 infection
Chun-jing 2012 [47]	No serious adverse events Adhesiolysis* failed in 6 cases without any significant change in epidural anterior space angiography or any nerve injury complication
Gerdesmeyer 2013 [44]	No serious adverse events 54 patients (34 lysis, 20 placebo) reported intra-procedural pain 5 patients (3 lysis, 2 control) reported swelling without clinical evidence 48 (42 lysis, 6 control) transient neurological deficits following intervention 2 (1 lysis, 1 control) dural punctures with shearing of external catheter coating
Gerdesmeyer 2021 [45]	None reported
Karm 2018 [18]	No serious adverse events Transient minor events (not tabulated): Pain after adhesiolysis (2–3 days) Paresthesia during adhesiolysis Pain with needle insertion
Manchikanti 2008 [25]	No serious adverse events
Manchikanti 2008 [26]	No serious adverse events
Manchikanti 2008 [27]	No serious adverse events
Manchikanti 2008 [28]	No serious adverse events
Manchikanti 2009 [24]	No adverse events noted
Manchikanti 2009 [20]	1 subarachnoid placement of the catheter identified in the adhesiolysis group
Manchikanti 2010 [29]	No serious adverse events
Manchikanti 2011 [30]	No serious adverse events
Manchikanti 2011 [31]	No serious adverse events
Manchikanti 2012 [32]	No serious adverse events
Manchikanti 2012 [33]	No serious adverse events
Manchikanti 2012 [23]	No serious adverse events 7 subarachnoid entries in adhesiolysis group 2 patients developed transient postoperative weakness
Manchikanti 2012 [34]	No serious adverse events
Manchikanti 2012 [35]	No serious adverse events
Manchikanti 2013 [19]	No serious adverse events 6 subarachnoid punctures 2 patients developed transient postoperative weakness
Manchikanti 2015 [36]	No serious adverse events
Park 2013 [48]	No serious adverse events 5 vasovagal (2 ultrasound, 3 fluoro) 3 transient headache (2 ultrasound, 1 fluoro) 9 transient pain (5 ultrasound, 4 fluoro)
Yousef 2010 [49]	No serious adverse events 4 minor complications (e.g., rash and itching)

TFESI- Transforaminal Epidural Steroid Injection; \*The term neuroplasty is used throughout the manuscript to describe procedures involving the use of a catheter where the intention was to chemically or mechanically “lyse” adhesions or resolve a filling defect. In this table the authors’ preferred term is used.

represented in studies in this systematic review: 1) radiculopathy with disc herniation, 2) CPSBP, 3) central lumbar spinal stenosis with neurogenic claudication, 4) discogenic CLBP, and 5) CLBP without disc herniation/radiculitis. However, the similarities of the studies addressed herein end there.

A variety of techniques and injected medications have been studied for caudal ESIs, more so than interlaminar ESIs or transforaminal ESIs. However, the associated body of literature has not been developed enough to establish a definitive superiority of a specific procedural technique or epidural injectate. This leads to ambiguity when

interpreting the available literature. [Table 1](#) describes the 23 different studies that were included in this review, the majority of which include entirely different methods for performing this procedure. For this reason, the authors were unable to perform a meta-analysis. Because of the heterogeneity in the technique for caudal ESI, it is possible that the subtle differences may have contributed to increased or decreased benefit as compared to steroid in isolation. Additionally, 16/23 (70%) of the studies had the same first author, which limits generalizability of findings. Many of the included studies used the “last data point carried forward” method to complete an intention-to-treat analysis, wherein a

dropout's score was carried forward throughout the duration of the study, as opposed to accounting for the dropout as a failure. The categorical data within these studies therefore cannot be fairly evaluated, which left only three articles with interpretable categorical data [18,44,45].

Of the three articles with interpretable categorical data, data from the two articles describing the same population support the notion that caudal ESIs may be a viable option for the treatment of radiculopathy with disc herniation, CPSBP, and lumbar spinal stenosis with claudication [44,45]. In Gerdesmeyer et al., the only explanatory RCT with viable categorical data, there was a statistically and clinically meaningful improvement in pain and function at three, six, and 12 months. If a similar study demonstrates comparable results, the reproducibility of findings would likely increase confidence in the results and justify a GRADE quality of evidence rating of "high". Of note, it is unclear what the role of the included injectates other than steroid may have played in the outcomes in this study. Perhaps most importantly, Gerdesmeyer et al. implemented a two-day in-dwelling catheter neuroplasty technique, which is not commonly used due to the necessity of inpatient hospitalization.

In the one other available article with interpretable categorical data, because the main difference between the two groups in Karm et al. was the use of a catheter with a balloon versus a catheter without a balloon, this study amounts to two separate cohort studies of two distinct types of epidural neuroplasty [18]. Therefore, the findings are less meaningful relative to a prospective trial comparing caudal ESI or epidural neuroplasty to a sham procedure or any type of standard care for the condition of interest.

Given the noted heterogeneity and lack of conclusive results relative to the various diagnoses studied, it is clear that more research is needed to understand the utility of caudal ESI and epidural neuroplasty in the treatment of painful conditions of the lumbosacral spine. This research should include, but is not limited to, appropriate diagnosis/diagnoses for the procedure, optimal timeframe of intervention, precise location(s) of injectate delivery, injectate type(s), catheter use, catheter type, and optimal duration of use of the catheter (if any).

There are several limitations to the present review. It is possible that all relevant data were not captured. Useful data may have been rejected if unavailable in English. Reviewers are also susceptible to confirmation bias and their assessments can be influenced by their previous experience and knowledge of a procedure and its effects. With access to raw data, the possibility exists that several of the studies with published categorical data may have been interpretable and thus added to the body of outcomes for explanatory studies. We did not contact authors to request raw data. Lastly, our review was not exhaustive regarding a review of retrospective case studies, case series, and case studies to assess for other adverse events associated with caudal ESIs and epidural neuroplasty. Rare complications, by definition, are not captured in cohort studies aside from very large registries, which do not exist for these procedures.

## 5. Conclusion

The published evidence establishes that when the inclusion criteria utilized for this systematic review are applied, caudal epidural neuroplasty performed using an indwelling catheter for two days with a specific epidural injectate described by Gerdesmeyer et al. are effective treatments for lumbosacral radiculopathy with disc herniation and for CPSBP, though the GRADE level of certainty is *moderate* only for this variant of the procedure. For all other methods of performing caudal ESIs described in the present literature, the level of evidence is *low* for the treatment of pain and dysfunction associated with central lumbar spinal stenosis with neurogenic claudication, discogenic CLBP, and CLBP without disc herniation/radiculitis, and the available evidence supports a possible benefit. More research is needed to understand the utility of caudal ESI/neuroplasty in the treatment of painful conditions of the lumbosacral spine. This research should include, but is not limited to, appropriate diagnosis/diagnoses for the procedure, optimal timeframe of

intervention, location(s) of injectate delivery, injectate type(s), injectate volume, catheter use, catheter type, and optimal duration of use of a catheter (if any).

## Funding

No funding was received for this systematic review.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Acknowledgements

The authors would like to acknowledge Dr. Arsenio Avila for his assistance early in the review process with reviewing a subset of abstracts and participating in discussions regarding the scope of the review. We also wish to thank the Spine Intervention Society's Standards Division and Evidence Analysis Committee for their careful review and thoughtful feedback on this manuscript.

## References

- [1] Goebert Jr HW, Jallo SJ, Gardner WJ, Wasmuth CE. Painful radiculopathy treated with epidural injections of procaine and hydrocortisone acetate: results in 113 patients. *Anesth Analg* 1961;40:130–4.
- [2] Bogduk N, editor. Practice guidelines for spinal diagnostic and treatment procedures. second ed. San Francisco: International Spine Intervention Society; 2013.
- [3] Smith CC, McCormick ZL, Mattie R, MacVicar J, Duszynski B, Stojanovic MP. The effectiveness of lumbar transforaminal injection of steroid for the treatment of radicular pain: a comprehensive review of the published data. *Pain Med* 2020; 21(3):472–87. <https://doi.org/10.1093/pm/pnz160>.
- [4] Sharma AK, Vorobeychik Y, Wasserman R, et al. The effectiveness and risks of fluoroscopically guided lumbar interlaminar epidural steroid injections: a systematic review with comprehensive analysis of the published data. *Pain Med* 2017;18(2):239–51. <https://doi.org/10.1093/pm/pnw131>.
- [5] Clements N, Vydra D, Cushman DM, et al. Trends in steroid agent and diluent choices for epidural steroid injections: a survey of Spine Intervention Society physicians [published online ahead of print, 2019 May 24]. *Reg Anesth Pain Med*; 2019. <https://doi.org/10.1136/rapm-2018-100366>. :rapm-2018-100366.
- [6] Conn A, Buenaventura RM, Datta S, Abdi S, Diwan S. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009;12(1):109–35.
- [7] Andreisek G, Jenni M, Klingler D, Wertli M, Elliott M, Ulbrich EJ, Winkhofer S, Steurer J. Access routes and reported decision criteria for lumbar epidural drug injections: a systematic literature review. *Skeletal Radiol* 2013;42(12):1683–92.
- [8] Johnson BA, Schellhas KP, Pollei SR. Epidurography and therapeutic epidural injections: technical considerations and experience with 5334 cases. *AJNR Am J Neuroradiol* 1999;20(4):697–705.
- [9] Benyamin RM, Manchikanti L, Parr AT, Diwan S, Singh V, Falco FJ, Datta S, Abdi S, Hirsch JA. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician* 2012;15(4):E363–404.
- [10] Oh CH, Ji GY, Cho PG, Choi WS, Shin DA, Kim KN, Kang HA. The catheter tip position and effects of percutaneous epidural neuroplasty in patients with lumbar disc disease during 6-months of follow-up. *Pain Physician* 2014;17(5):E599–608.
- [11] Smith C, Sudhakaran S, McCormick ZL. Spine Intervention Society's Patient Safety Committee. Is there a risk of neurological complications due to vascular infarction associated with particulate steroid use during interlaminar epidural steroid injections? *Pain Med* 2021;22(1):212–3. <https://doi.org/10.1093/pm/pnaa310>.
- [12] Kennedy DJ, Plastaras C, Casey E, et al. Comparative effectiveness of lumbar transforaminal epidural steroid injections with particulate versus nonparticulate corticosteroids for lumbar radicular pain due to intervertebral disc herniation: a prospective, randomized, double-blind trial. *Pain Med* 2014;15(4):548–55. <https://doi.org/10.1111/pme.12325>.
- [13] Park CH, Lee SH, Kim BI. Comparison of the effectiveness of lumbar transforaminal epidural injection with particulate and nonparticulate corticosteroids in lumbar radiating pain. *Pain Med* 2010;11(11):1654–8. <https://doi.org/10.1111/j.1526-4637.2010.00941.x>.
- [14] Schneider BJ, McCormick ZL, Smith CC. Spine Intervention Society's Patient Safety Committee. Particulate or nonparticulate steroids for lumbar transforaminal injections. *Pain Med* 2017;18(9):1817–8. <https://doi.org/10.1093/pm/pnx171>.
- [15] Cleary M, Keating C, Poynton AR. The flow patterns of caudal epidural in upper lumbar spinal pathology. *Eur Spine J* 2011;20(5):804–7. <https://doi.org/10.1007/s00586-010-1613-5>.

- [16] Racz GB, Holubec JT. Lysis of adhesions in the epidural space. In: Racz GB, editor. *Techniques of neurolysis*. Boston, MA: Springer US; 1989. p. 57–72.
- [17] Heavner JE, Racz GB, Raj P. Percutaneous epidural neurolysis: prospective evaluation of 0.9% NaCl versus 10% NaCl with or without hyaluronidase. *Reg Anesth Pain Med* 1999;24(3):202–7.
- [18] Karm MH, Choi SS, Kim DH, Park JY, Lee S, Park JK, Suh YJ, Leem JG, Shin JW. Percutaneous epidural adhesiolysis using inflatable balloon catheter and balloonless catheter in central lumbar spinal stenosis with neurogenic claudication: a randomized controlled trial. *Pain Physician* 2018;21(6):593–606.
- [19] Manchikanti L, Cash KA, McManus CD, Pampati V. Assessment of effectiveness of percutaneous adhesiolysis in managing chronic low back pain secondary to lumbar central spinal canal stenosis. *Int J Med Sci* 2013;10(1):50–9.
- [20] Manchikanti L, Cash KA, McManus CD, Pampati V, Singh V, Benyamin R. The preliminary results of a comparative effectiveness evaluation of adhesiolysis and caudal epidural injections in managing chronic low back pain secondary to spinal stenosis: a randomized, equivalence controlled trial. *Pain Physician* 2009;12(6):E341–54.
- [21] Manchikanti L, Pampati V, Cash KA. Protocol for evaluation of the comparative effectiveness of percutaneous adhesiolysis and caudal epidural steroid injections in low back and/or lower extremity pain without post surgery syndrome or spinal stenosis. *Pain Physician* 2010;13(2):E91–110.
- [22] Manchikanti L, Rivera JJ, Pampati V, Damron KS, McManus CD, Brandon DE, Wilson SR. One day lumbar epidural adhesiolysis and hypertonic saline neurolysis in treatment of chronic low back pain: a randomized, double-blind trial. *Pain Physician* 2004;7(2):177–86.
- [23] Manchikanti L, Singh V, Cash KA, Pampati V. Assessment of effectiveness of percutaneous adhesiolysis and caudal epidural injections in managing post lumbar surgery syndrome: 2-year follow-up of a randomized, controlled trial. *J Pain Res* 2012;5:597–608.
- [24] Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. A comparative effectiveness evaluation of percutaneous adhesiolysis and epidural steroid injections in managing lumbar post surgery syndrome: a randomized, equivalence controlled trial. *Pain Physician* 2009;12(6):E355–68.
- [25] Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV. Preliminary results of a randomized, equivalence trial of fluoroscopic caudal epidural injections in managing chronic low back pain: Part 2–Disc herniation and radiculitis. *Pain Physician* 2008;11(6):801–15.
- [26] Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. Preliminary results of a randomized, equivalence trial of fluoroscopic caudal epidural injections in managing chronic low back pain: Part 3–Post surgery syndrome. *Pain Physician* 2008;11(6):817–31.
- [27] Manchikanti L, Cash KA, McManus CD, Pampati V, Abdi S. Preliminary results of a randomized, equivalence trial of fluoroscopic caudal epidural injections in managing chronic low back pain: Part 4–Spinal stenosis. *Pain Physician* 2008;11(6):833–48.
- [28] Manchikanti L, Cash KA, McManus CD, Pampati V, Smith HS. Preliminary results of a randomized, equivalence trial of fluoroscopic caudal epidural injections in managing chronic low back pain: Part 1–Discogenic pain without disc herniation or radiculitis. *Pain Physician* 2008;11(6):785–800.
- [29] Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. Management of pain of post lumbar surgery syndrome: one-year results of a randomized, double-blind, active controlled trial of fluoroscopic caudal epidural injections. *Pain Physician* 2010;13(6):509–21.
- [30] Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV. A randomized, controlled, double-blind trial of fluoroscopic caudal epidural injections in the treatment of lumbar disc herniation and radiculitis. *Spine* 2011;36(23):1897–905.
- [31] Manchikanti L, Cash KA, McManus CD, Pampati V, Smith HS. One-year results of a randomized, double-blind, active controlled trial of fluoroscopic caudal epidural injections with or without steroids in managing chronic discogenic low back pain without disc herniation or radiculitis. *Pain Physician* 2011;14(1):25–36.
- [32] Manchikanti L, Cash KA, McManus CD, Pampati V, Fellows B. Results of 2-year follow-up of a randomized, double-blind, controlled trial of fluoroscopic caudal epidural injections in central spinal stenosis. *Pain Physician* 2012;15(5):371–84.
- [33] Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. Fluoroscopic caudal epidural injections in managing post lumbar surgery syndrome: two-year results of a randomized, double-blind, active-control trial. *Int J Med Sci* 2012;9(7):582–91.
- [34] Manchikanti L, Cash KA, McManus CD, Pampati V, Fellows B. Fluoroscopic caudal epidural injections with or without steroids in managing pain of lumbar spinal stenosis: one-year results of randomized, double-blind, active-controlled trial. *J Spinal Disord Tech* 2012;25(4):226–34.
- [35] Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV. Effect of fluoroscopically guided caudal epidural steroid or local anesthetic injections in the treatment of lumbar disc herniation and radiculitis: a randomized, controlled, double blind trial with a two-year follow-up. *Pain Physician* 2012;15(4):273–86.
- [36] Manchikanti L, Pampati V, Benyamin RM, Boswell MV. Analysis of efficacy differences between caudal and lumbar interlaminar epidural injections in chronic lumbar axial discogenic pain: local anesthetic alone vs. local combined with steroids. *Int J Med Sci* 2015;12(3):214–22.
- [37] Manchikanti L, Knezevic E, Knezevic NN, Sanapati MR, Thota S, Abd-Elsayed A, Hirsch JA. Epidural injections for lumbar radiculopathy or sciatica: a comparative systematic review and meta-analysis of cochrane review. *Pain Physician* 2021;24(5). E539–e54.
- [38] Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, Bryce DA, Burks PA, Caraway DL, Calodney AK, Cash KA, Christy PJ, Cohen SP, Colson J, Conn A, Cordero H, Coubarous S, Datta S, Deer TR, Diwan S, Falco FJ, Fellows B, Geffert S, Grider JS, Gupta S, Hameed H, Hameed M, Hansen H, Helm 2nd S, Janata JW, Justiz R, Kaye AD, Lee M, Manchikanti KN, McManus CD, Onyewu O, Parr AT, Patel VB, Racz GB, Sehgal N, Sharma ML, Simopoulos TT, Singh V, Smith HS, Snook LT, Swicegood JR, Vallejo R, Ward SP, Wargo BW, Zhu J, Hirsch JA. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician* 2013;16(2 Suppl):S49–283.
- [39] Parr AT, Manchikanti L, Hameed H, Conn A, Manchikanti KN, Benyamin RM, Diwan S, Singh V, Abdi S. Caudal epidural injections in the management of chronic low back pain: a systematic appraisal of the literature. *Pain Physician* 2012;15(3):E159–98.
- [40] Jamison DE, Hsu E, Cohen SP. Epidural adhesiolysis: an evidence-based review. *J Neurosurg Sci* 2014;58(2):65–76.
- [41] Bogduk N, Kennedy DJ, Vorobeychik Y, Engel A. Guidelines for composing and assessing a paper on treatment of pain. *Pain Med* 2017;18(11):2096–104.
- [42] Balshem H, Helfand M, Schunemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol* 2011;64(4):401–6.
- [43] Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008;336(7650):924–6.
- [44] Gerdemeyer L, Wagenpfeil S, Birkenmaier C, Veihelmann A, Hauschild M, Wagner K, et al. Percutaneous epidural lysis of adhesions in chronic lumbar radicular pain: a randomized, double-blind, placebo-controlled trial. *Pain Physician* 2013;16(3):185–96.
- [45] Gerdemeyer L, Noe C, Prehn-Kristensen A, et al. Long-term efficacy of percutaneous epidural neurolysis of adhesions in chronic lumbar radicular pain: 10 year follow-up of a randomized controlled trial. *Pain Physician* 2021;24(5):359–67.
- [46] Akbas M, Elawamy AR, Salem HH, Fouad AZ, Abbas NA, Dagistan G. Comparison of 3 approaches to percutaneous epidural adhesiolysis and neurolysis in post lumbar surgery syndrome. *Pain Physician* 2018;21(5):E501–8.
- [47] Chun-jing H, Hao-xiong N, jia-xiang N. The application of percutaneous lysis of epidural adhesions in patients with failed back surgery syndrome. *Acta Cir Bras* 2012;27(4):357–62.
- [48] Park Y, Lee JH, Park KD, Ahn JK, Park J, Jee H. Ultrasound-guided vs. fluoroscopy-guided caudal epidural steroid injection for the treatment of unilateral lower lumbar radicular pain: a prospective, randomized, single-blind clinical study. *Am J Phys Med Rehabil* 2013;92(7):575–86.
- [49] Yousef AA, AS EL-D, Al-Deeb AE. The role of adding hyaluronidase to fluoroscopically guided caudal steroid and hypertonic saline injection in patients with failed back surgery syndrome: a prospective, double-blinded, randomized study. *Pain Pract* 2010;10(6):548–53.
- [50] Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *J Pain: Off J Am Pain Soc* 2008;9(2):105–21.
- [51] Smith SM, Dworkin RH, Turk DC, McDermott MP, Eccleston C, Farrar JT, Rowbotham MC, Bhagwagar Z, Burke LB, Cowan P, Ellenberg SS, Evans SR, Freeman RL, Garrison LP, Iyengar S, Jadad A, Jensen MP, Junor R, Kamp C, Katz NP, Kessler JP, Kopecky EA, Lissin D, Markman JD, Mease PJ, O'Connor AB, Patel KV, Raja SN, Sampaio C, Schoenfeld D, Singh J, Steigerwald I, Strand V, Tive LA, Tobias J, Wasan AD, Wilson HD. Interpretation of chronic pain clinical trial outcomes: IMMPACT recommended considerations. *Pain* 2020 Nov;161(11):2446–61. <https://doi.org/10.1097/j.pain.0000000000001952>. PMID: 32520773; PMCID: PMC7572524.