International Centre for Allied Health Evidence

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Systematic Review of the Literature

Systematic Review: Injection of Steroid via the Caudal Sacral Route

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EXECUTIVE SUMMARY

Objective of the Review

The objective of this review is to synthesise the evidence related to the effectiveness of injection of steroid with or without local anaesthetic via the caudal sacral route as a form of interventional pain management. This review will carry out a systematic review of the best available research evidence.

This review aims to answer the following research questions:

a) What is the evidence for the effectiveness of caudal sacral epidural steroid injections with or without local anaesthetic in relieving pain?
b) What is the evidence for the effectiveness of caudal sacral epidural steroid injections with or without local anaesthetic in improving functional outcomes in patients?
c) What is the evidence for the safety of caudal sacral epidural steroid injections with or without local anaesthetic?

Evidence sourced

The search yielded 9619 articles; following removal of duplicates 5161 articles were identified for screening of title and abstract. After scrutiny, 5125 articles were excluded for failing to meet the inclusion criteria, leaving 36 studies for inclusion in this review, including two systematic reviews and five randomised controlled trials.

a) What is the evidence for the effectiveness of caudal sacral epidural steroid injections with or without local anaesthetic in relieving pain?

1. Caudal sacral epidural injections appear to be effective in the management of chronic low back pain when compared to conservative management (Evidence level A).
2. There is conflicting evidence of the efficacy of the addition of steroid to local anaesthetic via the caudal route; efficacy may be dependent on the specific condition, and further research is required (Evidence level D).
3. A single study reported the cost utility of caudal sacral epidural steroids at $2,200 per quality-adjusted life year, suggesting that this is a cost-effective intervention in the management of low back pain. However, this was not compared to conservative treatment or the other techniques of lumbar epidural injection (Evidence level B)

b) What is the evidence for the safety of caudal sacral epidural steroid injections with or without local anaesthetic?

1. Of the three lumbar epidural techniques the caudal sacral route appears to be the easiest and safest route, although it appears that the other methods may be more effective. The caudal sacral route should be considered in patients at higher risk of complications such as elderly frail patients and in those who cannot be safely positioned for the other techniques as patients can be positioned in either the prone or side lying position for a caudal epidural (Evidence level A)
2. Caudal sacral epidural injections should be conducted under radioscopic guidance, in order to avoid potential complications such as missing the epidural space (Evidence level A). There does not appear to be a difference between ultrasound or fluoroscopically guided epidural. However, this is based on a single small study and therefore further research is required (Evidence level D)

1. Background

1.1 Objective of this Review

The objective of this review is to synthesise the evidence related to the effectiveness of injection of a steroid with or without local anaesthetic via the caudal sacral route as a form of interventional pain management. This review will carry out a systematic review of the best available research evidence.
This review aims to answer the following research questions:

a) What is the evidence for the effectiveness of caudal sacral epidural steroid injections with or without local anaesthetic in relieving pain?
b) What is the evidence for the effectiveness of caudal sacral epidural steroid injections with or without local anaesthetic in improving functional outcomes in patients?
c) What is the evidence for the safety of caudal sacral epidural steroid injections with or without local anaesthetic?

1.2 Description of the Intervention

Epidural injections for lower back and leg pain are predominantly administered in one of three ways including interlaminar, transforaminal and caudal sacral. The caudal sacral approach to the epidural space is the earliest known technique for epidural steroid injections and blocks (Ogoke 2000). In 1952 corticosteroid was added to a local anaesthetic injectate mixture and used specifically for management of acute and chronic pain (Ogoke 2000). There are significant differences between the three techniques, with the caudal sacral epidural considered to be the safest and easiest of the three (Conn, Buenaventura et al. 2009; Manchikanti, Boswell et al. 2009).

Caudal sacral epidural steroid injection can be administered to the patient in a prone position or on their side, with the hip flexed (Ogoke 2000). Following prepping and draping, the sacral hiatus area is infiltrated with local anaesthetic at the skin level using a 25 gauge x 1.5” needle. A 45-degree angle of entry of the epidural needle should be accompanied by radiographic confirmation to avoid needle misplacement difficulties such as missing the sacral epidural space (Ogoke 2000). Following radiographic confirmation, the needle is then slowly but carefully advanced rostrally. After puncture of the sacral hiatus, the angle of the entire needle is slowly reduced.

The needle is then slowly advanced into the epidural space; the correct location can be confirmed by the loss-of-resistance technique using a puff of air or saline. A total of 5ml to 25ml of injectate is commonly used, depending on stature and frailty of the patient (Ogoke 2000).

Caudal sacral epidural steroid injections, at the lumbar level, may be indicated for (Ogoke 2000):

- Annular tear (back sprain)
- Herniated disc
- Chemical neuritis
- Internal disc disruption syndrome
- Scoliosis
- Spinal stenosis
- Sciatica

1.3 Safety/Risk

While caudal sacral epidural steroid injections are considered to be the safest and easiest route, with minimal risk, especially when conducted under radiographic guidance, there remains some risk. Ogoke (2000) compiled a comprehensive list of potential complications and side effects of caudal sacral steroid epidurals, although they failed to provide any evidence of these occurring:

1. Infection;
2. Post injection pain at the site of entry (usually does not exceed 2-6 months);
3. Intrathecal injection;
4. Nerve injury (rare);
5. Intravascular or intraosseous injection may lead to toxicity of local anaesthetic.

2. Methodology

2.1 Review question

What is the effectiveness of caudal sacral epidural injection of steroid with or without local anaesthetic?

2.2 Methods

A systematic review of published research literature was undertaken to provide a synthesis of the currently available research evidence related to the effectiveness of caudal sacral epidural steroid injections with or without local anaesthetic as a form of interventional pain management. A systematic and rigorous search strategy was developed to locate all published and accessible research evidence. The evidence base for this review included research evidence from existing systematic reviews, meta-analyses, and high-level primary research (randomised controlled trials, prospective cohort studies). Where no systematic reviews, randomised controlled trials, or prospective cohort studies were located then other primary study designs (excluding commentary /expert opinion) were considered.

The search was developed using a standard PICO structure (shown in Table 1). Only English articles published, using human participants, which were accessible in full text were included.

Table 1: Criteria for considering studies in the review

Population	Humans
Intervention	Epidural steroid injection with or without local anaesthetic via the caudal sacral route as a form of interventional pain management
Comparator	Any active treatment or placebo.
Outcomes	• Pain-related primary outcome • Functional outcomes (range of motion, reduction of disability, return to work, quality of life) • Safety and Risk • Relationship to Imaging • Best Practice recommendations • Cost effectiveness

2.3 Search strategy

A combination of search terms (shown in Table 2) were used to identify and retrieve articles in the following databases:

- OVID
  - EMBASE,
  - MEDLINE,
  - AMED,
- ICONDA,
- CINAHL,
- PubMed,
- Pre-Medline,
- The Cochrane Library,
- Scopus,
- TRIP database

2.4 Study Selection

Table 2: Search terms for the review

Search term 1	Search terms 2	Search terms 2	Search terms 3
• Pain	• Injections • Epidural • Spinal • Intra-articular .	• Sacral • Caudal • Epidural space • Lumbar • Sacroiliac joint • Intervertebral disc • Spinal canal	• Steroid • Betamethasone • Dexamethasone • Fluocortolone • Methylprednisolone • Paramethasone • Prednisolone • Prednisone • Triamcinolone • Hydrocortisone • Cortisone • Methandrostenolone • Stanozolol • Methenolone • Oxymetholone • Oxandrolone • Nandrolone • Diflucortolone • Fluprednisolone

The titles and abstracts identified from the above search strategy were assessed for eligibility by the *i*CAHE researchers. Full-text copies of eligible articles were retrieved for full examination. Reference lists of included full-text articles were searched for relevant literature not located through database searching.

Inclusion Criteria

1. Study Types: Systematic Reviews, all Primary research designs (Randomised Controlled Trials (RCTs), Cohort studies (Prospective or Retrospective), Case Studies or Case Series.
2. Participants: Patients with lower back or lower limb pain.
3. Intervention: Steroid injections with or without local anaesthetic via the caudal sacral route.
4. Controls: any active treatment or placebo, or no intervention control
5. Outcomes: Pain relief (primary) functional outcomes, safety, and risk (secondary)
6. Publication criteria – English language, full text available, in peer reviewed journal.

Exclusion criteria

1. Studies only available in abstract form e.g. conference presentations
2. Grey literature and non-English language material
3. Studies involving healthy volunteers or experimentally induced pain
4. Studies on interventions involving other epidural techniques where caudal sacral could not be differentiated.

2.5 Critical Appraisal

The SIGN (Scottish Intercollegiate Guidelines Network) checklist specific to the study design of the included studies was used to assess the methodological quality of the included studies. The SIGN checklist asks a number of questions with yes, no, can't say or not applicable as responses with the appraiser giving an overall rating of quality, based on the responses to questions of either high quality (++), acceptable (+), low quality (-) or unacceptable. As there is no SIGN Checklist for Case studies these study designs will not be quality scored.

2.6 Data Extraction

Data was extracted from the identified publications using a data extraction tool which was specifically developed for this review. The following information was extracted from individual studies:

- Evidence source (Author, date, country)
- Level of evidence
- Characteristics of participants
- Interventions
- Outcome measures
- Results

2.7 Data Synthesis

For this review the studies that met the inclusion criteria were assessed for internal validity using the Scottish Intercollegiate Guidelines network (SIGN) Checklist for the relevant study design. Each study was graded for overall methodological quality using the SIGN Levels of evidence model.

Table 3: SIGN Evidence Grading Matrix

Levels of scientific evidence	
1++	High-quality meta-analyses, high-quality systematic reviews of clinical trials with very little risk of bias.
1+	Well-conducted meta-analyses, systematic review of clinical trials or well-conducted clinical trials with low risk of bias.
1-	Meta-analyses, systematic reviews of clinical trials or clinical trials with high risk of bias.
2++	High-quality systematic reviews of cohort or case and control studies; cohort or case and control studies with very low risk of bias and high probability of establishing a causal relationship.
2+	Well-conducted cohort or case and control studies with low risk of bias and moderate probability of establishing a causal relationship.
2-	Cohort or case and control studies with high risk of bias and significant risk that the relationship is not causal.
3	Non-analytical studies, such as case reports and case series.
4	Expert opinion.

2.8 Grade of Recommendations

Recommendations will be graded according to the Scottish Intercollegiate Guidelines network (SIGN) Grades of Recommendations (Table 4)

Table 4: Scottish Intercollegiate Guidelines network (SIGN) Grades of Recommendations

Grades of Recommendations	
A	At least one meta-analysis, systematic review or clinical trial classified as 1++ and directly applicable to the target population of the guideline, or a volume of scientific evidence comprising studies classified as 1+ and which are highly consistent with each other.
B	A body of scientific evidence comprising studies classified as 2++, directly applicable to the target population of the guideline and highly consistent with each other, or scientific evidence extrapolated from studies classified as 1++ or 1+.
C	A body of scientific evidence comprising studies classified as 2+, directly applicable to the target population of the guideline and highly consistent with each other, or scientific evidence extrapolated from studies classified as 2++.
D	Level 3 or 4 scientific evidence, or scientific evidence extrapolated from studies classified as 2+.

3. Results

3.1 Evidence Sources

The search yielded 9619 articles; following removal of duplicates 5161 articles were identified for screening of title and abstract. After scrutiny, 5125 articles were excluded for failing to meet the inclusion criteria (shown in Figure 1), leaving 36 studies for inclusion in this review. Figure 1 illustrates the process involved in study selection.

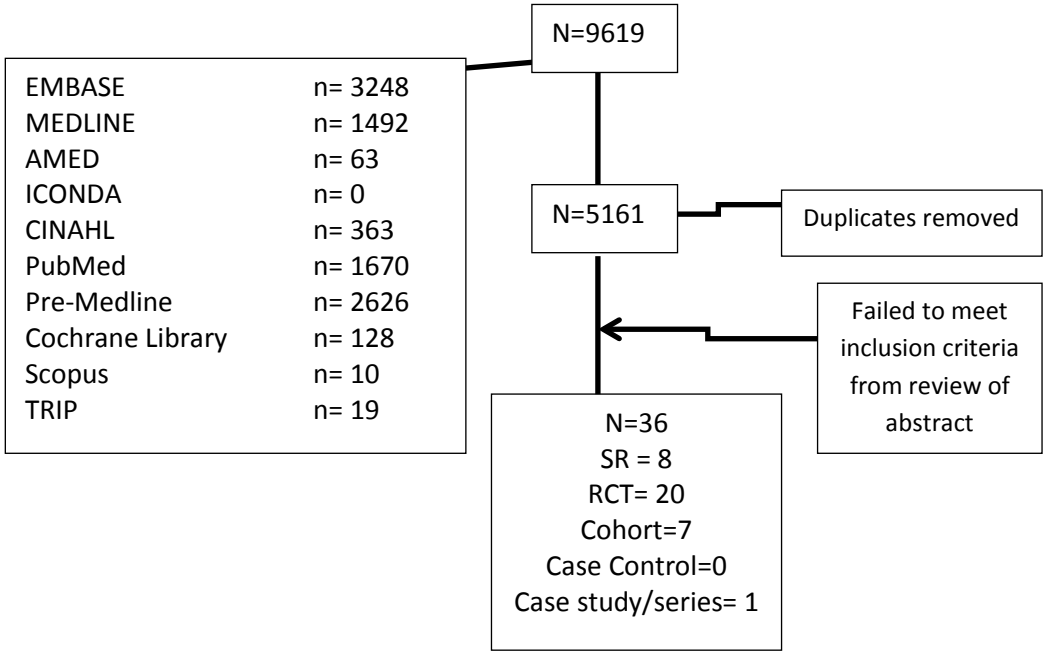

Figure 1: Flow chart of search results

Only the highest level of evidence was included in the review, therefore because high quality systematic reviews and randomized controlled trials were located cohort and case studies were excluded. Of the eight systematic reviews located, only the most recent high-quality systematic reviews (Parr, Manchikanti et al. 2012; Liu, Zhou et al. 2016) were included. The other systematic reviews were excluded as the overall focus was not caudal sacral steroid epidural (Abdi, Datta et al. 2005; Bhargava, DePalma et al. 2005; Colimon and Villalobos 2010; Cohen, Bicket et al. 2013; Shamliyan, Staal et al. 2014) or they were deemed to be of acceptable or lower quality (Friedman and Dighe 2013). A total of 20 randomised controlled trials were located however given the high quality of the systematic reviews located, randomised controlled trials were only included if they were published between 2011 and 2016 and were not already included in at least one of the two systematic reviews (n=5).

3.2 Quality of the Evidence

The overall quality of the studies included in this review ranged from High Quality to Low Quality. The two systematic reviews were of High Quality (1++); however the quality of the Randomised Controlled Trials published between 2011 and 2016 that were not included in the two systematic reviews were low to acceptable quality.

3.3 Findings

Two systematic reviews of high quality were located that specifically investigated the efficacy of caudal sacral epidural steroid injections. The systematic review published in 2016 (Liu, Zhou et al. 2016) specifically compared transforaminal versus caudal sacral routes; while the 2012 review (Parr, Manchikanti et al. 2012) was a more broad review of cudal sacral epidural injections for chronic low back pain. A further four randomised controlled trials published between 2012 and 2016 that were not included in either systematic review were also located (Datta and Upadhyay 2011; Murakibhavi and Khemka 2011; Park, Lee et al. 2013; Pandey 2016). Only one economic study that specifically investigated caudal sacral epidural steroid injections was located (Manchikanti, Falco et al. 2013). Full details of individual studies can be found in Appendix 4 (Full data extraction).

3.4 Outcome Measures – Pain and Function

Systematic Reviews

Parr et al. (2012) reviewed the literature to determine the efficacy of caudal sacral injections with or without steroids, with or without fluoroscopy and for various conditions affecting the lower back such as disc herniation and spinal stenosis. The authors concluded that there was good evidence caudal sacral epidural injections are effective in managing chronic low back and lower extremity pain caused by disc herniation with radiculitis. However, the evidence for spinal stenosis, axial pain, and post surgery syndrome was inconclusive. While the review found evidence of effectiveness in caudal sacral route epidural injections, there was not a significant difference in effectiveness between local anaesthetic with and without a steroid.

Study	QS	Conclusions	Level of Evidence
Parr et al. (2012)	A (++)	• Caudal epidural injections with or without steroids has shown good evidence for short- and long-term relief of chronic pain secondary to disc herniation or radiculitis with local anaesthetic and steroids and fair evidence of relief with local anaesthetic only. • There is some evidence for the effectiveness of caudal epidural injections in managing chronic axial or discogenic pain, spinal stenosis, and post surgery syndrome.	1 1-

Liu et al. (2016) compared the effectiveness of transforaminal to caudal sacral routes for epidural steroid injections for the treatment of radiculopathy. Authors reported that the transforaminal route appears to be more effective in the short-term (<6 months); however long-term (>12 months) the caudal sacral route appears to be slightly more effective, although differences were not statistically significant. Due to the small sample size and methodological concerns of studies included in the systematic review, the results should be interpreted with caution.

Study	QS	Conclusions	Level of Evidence
Liu 2016	A (++)	• Transforaminal more effective short term • Caudal sacral route may be slightly more effective long term (no statistically significant difference)	1-

Randomised Controlled Trials

Pandey (2016) investigated the functional efficacy of the three different lumbar epidural techniques including caudal sacral, transforaminal and interlaminar. Researchers randomised 152 patients with back pain with or without radiculopathy with a lumbar disc prolapse into three groups. All groups received differing amounts of methylprednisolone depending on the epidural method. Authors concluded that all three techniques were effective; however, the best results were found in the transforaminal route group.

Study	QS	Conclusions
Pandey (2016)	LQ (-)	• At one year after steroid injection, all three routes were found to be effective in improving function. • Transforaminal route was significantly more effective than caudal sacral (p=0.00) and interlaminar route (p=0.03) at both 6 months and one year after injection. • No significant difference was seen between the caudal sacral and interlaminar route (p=0.36).

Park et al. (2013) investigated the short-term pain relief and functional improvements of ultrasound guided compared to fluoroscopically guided caudal sacral epidural steroid injections in 110 patients. Authors concluded that the ultrasound approach with Doppler mode may avoid intravascular injection-induced complications. There were similar improvements in short-term pain relief, function, and patient satisfaction with both ultrasound and fluoroscopically guided caudal epidural injections.

Study	QS	Conclusions
Park et al (2013)	A (+)	• No differences in outcome measures or effectiveness of the procedure between ultrasound-guided caudal sacral epidural steroid injections and fluoroscopy guided epidural steroid injections

Datta & Upadhyay (2011) investigated the efficacy of epidurals given via the caudal sacral route for sciatica comparing three different steroids. A total of 207 participants were randomly assigned to four groups including local anaesthetic (bupivacaine) alone, local anaesthetic plus methylprednisolone, local anaesthetic plus triamcinolone, and local anaesthetic plus dexamethasone. The authors concluded that caudal sacral epidural steroid injections are a simple, cost-effective and minimally invasive management strategy for sciatica due to prolapsed disc. All long-acting steroids were effective, but methylprednisolone and triamcinolone were found to be more effective than dexamethasone, which was also associated with more side-effects.

Study	QS	Conclusions
Datta & Upadhyay (2011)	A (+)	• Short term improvement in leg pain and sensory deficits were found in patients with sciatica with both epidural bupivacaine and steroids. • All long-acting steroids had no statistically significant difference between their efficacy in pain relief but methylprednisolone and triamcinolone were more effective by the second injection compared to dexamethasone.

Murakibhavi & Khemka (2011) investigated the efficacy of caudal sacral epidural injections in the management of chronic low back pain and sciatica. Researchers randomised 102 patients to conservative treatment (no epidural) or local anaesthetic combined with triamcinolone acetate (steroid). Authors concluded that caudal sacral epidural steroid injections seem to be effective for the treatment of low back pain and sciatica when compared to conservative treatment (including oral medication and physiotherapy). Caudal sacral epidurals are easy to perform, less technically demanding and low risk compared to conservative management.

Study	QS	Conclusions
Murakibhavi & Khemka (2011)	LQ (-)	• Caudal sacral epidural steroid injections seem to be effective when treating patients with low back pain and sciatica. • Caudal sacral epidural steroid injections are easy to perform, less technically demanding, and with low complications compared with conservative treatment.

3.5 Outcome Measures – Safety and Risk

Parr et al. (2012) reported that complications related to caudal sacral epidural injections are rare. Common complications are usually related to needle placement or related to the drug activity including infection, local or epidural abscess, discitis, intravascular injection, spinal cord infarction, subcutaneous injection, subdural injection, dural puncture potentially leading to lumbar puncture headache, nerve damage intracranial air injection or increased intracranial pressure.

Although the majority of studies reported no adverse events, complications reported in the studies included in this review including both individual studies and those included in the systematic reviews include:

- Insomnia the night of the injection (4.7%) (Parr, Manchikanti et al. 2012)
- Transient non-positional headaches (3.5%) (Parr, Manchikanti et al. 2012)
- Increased back pain (3.1%) (Parr, Manchikanti et al. 2012)
- Facial flushing (2.3%) (Parr, Manchikanti et al. 2012)
- Vasovagal reactions (0.8%) (Parr, Manchikanti et al. 2012) (1.6%) (Park, Lee et al. 2013)
- Nausea (0.8%) (Parr, Manchikanti et al. 2012)
- Increased leg pain (0.4%) (Parr, Manchikanti et al. 2012) (7.5%) (Liu, Zhou et al. 2016)
- Soreness at the injection site (Liu, Zhou et al. 2016)
- Temporary paraparisis (in one patient) (Liu, Zhou et al. 2016)

Other much less common complications include transient blindness, retinal haemorrhage and necrosis, serous chorioretinopathy, persistent recurrent intractable hiccups, flushing, chemical meningitis, arachnoiditis, discitis, epidural haematoma and epidural abscess (Parr, Manchikanti et al. 2012). Infection and post lumbar puncture headache were not reported in any of the studies investigating the caudal sacral epidural route.

3.6 Economic analysis

Manchikanti et al. (2013) investigated the cost utility of caudal sacral epidural injections in the management of chronic low back pain. The authors used data from four randomised controlled trials investigating the effectiveness of caudal sacral epidural injections with or without steroids. A cost utility analysis was performed with direct payment data (reimbursement data including payments for physician assessment for visits and facility expenses for procedures) for a total of 480 patients over a two year period. The authors concluded that caudal sacral epidural injections in the treatment of disc herniation, axial or discogenic low back pain, central spinal stenosis or post-surgery syndrome in the lumbar spine demonstrates cost- utility of these injections at less than $2,200 per one year of quality-adjusted life year.

Study	Conclusions
Manchikanti et al (2013)	• Caudal sacral epidural injections in the treatment of disc herniation, axial or discogenic low back pain, central spinal stenosis, and post-surgery syndrome in the lumbar spine are cost effective.

4. Recommendations

Grade of Recommendation:

1. Caudal sacral epidural injections appear to be effective in the management of chronic low back pain when compared to conservative management (Evidence level A).
2. There is conflicting evidence of the efficacy of the addition of steroid to anaesthetic via the caudal sacral route. Current research evidence is limited by lack of comparison between steroid and anaesthetic (Evidence level D, based on usual practice).
3. Of the three lumbar epidural techniques the caudal sacral route appears to be the easiest and safest route, although it appears that the other methods may be more effective. The caudal sacral route should be considered in patients at higher risk of complications such as elderly frail patients and in those who cannot be safely positioned for the other techniques as patients can be positioned in either the prone or side lying position for a caudal sacral epidural (Evidence level A).
4. Caudal sacral epidural injections should be conducted under radioscopic guidance, in order to avoid potential complications such as missing the epidural space (Evidence level A). There does not appear to be a difference between ultrasound or fluoroscopically guided epidural. However, this is based on a single small study and therefore further research is required (Evidence level D).
5. A single study reported the cost utility of caudal sacral epidural steroids at $2,200 per quality-adjusted life year, suggesting that this is a cost-effective intervention in the management of low back pain. However, this was not compared to conservative treatment or the other techniques of lumbar epidural injection (Evidence level B).

5. References

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Yongbum, P., L. Ji-Hae, et al. (2013). "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." American Journal of Physical Medicine & Rehabilitation 92(7): 575-586.

6. Appendices

Appendix 1 – Summary of Studies included in this review

Study Design	Author	Year	Level of Evidence	Quality score	N=	Outcomes	Conclusions
Systematic review	Parr et al.	2012	1++	11/13	N/A	Pain relief, functional status, return to work, psychological status and medication use	Caudal epidural injections are an effective management strategy for chronic low back pain. There was no difference between local anaesthetic with or without steroid.
Systematic review	Liu et al.	2016	1++	10/13	N/A	Pain and functional improvements	Both the transforaminal and caudal approaches are effective in reducing pain and improving functional scores.
RCT	Park et al.	2013	+	7/9	120	Verbal numerical rating scale (VNS), 5-point satisfaction scale, contrast pattern, ODI	The results showed similar improvements in short-term pain relief, function, and patient satisfaction with both ultra-sound and fluoroscopic guidance.
RCT	Pandey et al.	2016	-	5/9	152	Japanese Orthopaedic Association (JOA) Score	All 3 injection techniques are effective with the best result obtained by transforaminal route.
RCT	Datta et al.	2011	+	7/9	207	Pain visual analogue scale (VAS), Roland Morris low-back-pain disability questionnaire, straight leg raise and finger to floor distance	All long-acting steroids had no statistically significant difference between their efficacy in pain relief but methylprednisolone and triamcinolone were more effective by the second injection compared to dexamethasone.
RCT	Murakibhavi et al.	2011	-	5/9	102	Visual Analogue Scale (VAS), ODI, Beck depression inventory, numerical pain intensity questionnaire	Caudal epidural steroid injections seem to be effective when treating patients with low back pain and sciatica.
Economic study	Manchikanti et al.	2013			4 RCTs	Reimbursement data	The cost utility analysis of caudal epidural injections in the treatment of disc herniation, axial or discogenic low back pain, central stenosis, and post surgery syndrome in the lumbar spine shows the clinical effectiveness and cost utility of these injection at less than $2,200 per one year of QALY.

Appendix 2 – SIGN Checklists used in this review

SIGN Critical Appraisal Tool for Systematic Reviews and Meta-analyses

SIGN

Methodology Checklist 1: Systematic Reviews and Meta-analyses

SIGN gratefully acknowledges the permission received from the authors of the AMSTAR tool to base this checklist on their work: *Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C,. et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Medical Research Methodology 2007, **7**:10 doi:10.1186/1471-2288-7-10. Available from http://www.biomedcentral.com/1471-2288/7/10 [cited 10 Sep 2012]*

Study identification (*Include author, title, year of publication, journal title, pages*)	
Guideline topic:	Key Question No:

Before completing this checklist, consider:

Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO reject. IF YES complete the checklist.

Checklist completed by:

Section 1: Internal validity

In a well conducted systematic review:		***Does this study do it?***	
1.1	The research question is clearly defined and the inclusion/ exclusion criteria must be listed in the paper.	Yes □ **If no reject**	No □
1.2	A comprehensive literature search is carried out.	Yes □ Not applicable □ **If no reject**	No □
1.3	At least two people should have selected studies.	Yes □	No □ Can't say □
1.4	At least two people should have extracted data.	Yes □	No □ Can't say □
1.5	The status of publication was not used as an inclusion criterion.	Yes □	No □
1.6	The excluded studies are listed.	Yes □	No □
1.7	The relevant characteristics of the included studies are provided.	Yes □	No □
1.8	The scientific quality of the included studies was assessed and reported.	Yes □	No □
1.9	Was the scientific quality of the included studies used appropriately?	Yes □	No □
1.10	Appropriate methods are used to combine the individual study findings.	Yes □ Can't say □	No □ Not applicable □
1.11	The likelihood of publication bias was assessed appropriately.	Yes □	No □

		Not applicable □
1.12	Conflicts of interest are declared.	Yes □ No □
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	What is your overall assessment of the methodological quality of this review?	High quality (++) □ Acceptable (+) □ Low quality (-)□ Unacceptable – reject 0 □
2.2	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes □ No □
2.3	**Notes:**	

SIGN Critical Appraisal Tool for Controlled trials

Methodology Checklist 2: Controlled Trials

Study identification (*Include author, title, year of publication, journal title, pages*)		
Guideline topic:	Key Question No:	Reviewer:

Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+
2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

SECTION 1: INTERNAL VALIDITY

	In a well conducted RCT study…	***Does this study do it?***
1.1	The study addresses an appropriate and clearly focused question.	Yes ☐ No ☐ Can't say ☐
1.2	The assignment of subjects to treatment groups is randomised.	Yes ☐ No ☐ Can't say ☐
1.3	An adequate concealment method is used.	Yes ☐ No ☐ Can't say ☐
1.4	The design keeps subjects and investigators 'blind' about treatment allocation.	Yes ☐ No ☐ Can't say ☐
1.5	The treatment and control groups are similar at the start of the trial.	Yes ☐ No ☐ Can't say ☐
1.6	The only difference between groups is the treatment under investigation.	Yes ☐ No ☐ Can't say ☐
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	Yes ☐ No ☐ Can't say ☐
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes ☐ No ☐ Can't say ☐ Does not apply ☐
1.10	Where the study is carried out at more than one site, results are comparable for all sites.	Yes ☐ No ☐ Can't say ☐ Does not apply ☐

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1	How well was the study done to minimise bias?	High quality (++)☐

	Code as follows:	Acceptable (+)☐ Low quality (-)☐ Unacceptable – reject 0 ☐
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	
2.4	**Notes.** Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	

Appendix 3 – Quality scores for articles used in this review
SIGN Critical Appraisal Tool scores for Systematic Reviews

Quest	Reference (Author, year)	Liu et al. 2016	Parr et al. 2012
1.1	The research question is clearly defined and the inclusion/ exclusion criteria must be listed in the paper. Does this study do it?	Yes	Yes
1.2	A comprehensive literature search is carried out?	Yes	Yes
1.3	At least two people should have selected studies	Can't say	Yes
1.4	At least two people should have extracted the data	Yes	Yes
1.5	The status of publication was not used as an inclusion criterion	No	No
1.6	The excluded studies are listed	No	Yes
1.7	The relevant characteristics of the included studies are provided	Yes	Yes
1.8	The scientific quality of the included studies was assessed and reported.	Yes	Yes
1.9	Was the scientific quality of the included studies used appropriately?	Yes	Yes
1.10	Appropriate methods are used to combine the individual study findings	Yes	N/A
1.11	The likelihood of publication bias was assessed appropriately	Yes	Yes
1.12	Conflicts of interest are declared	Yes	Yes
2.1	What is your overall assessment of the methodological quality of this review?	++	++
2.2	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes	Yes

SIGN Critical Appraisal Tool scores for controlled trials

Quest	Reference (Author, year)	Datta et al. 2011	Park et al. 2013	Murakibhavi 2011	Pandey 2016
1.1	The study addresses an appropriate and clearly focused question.	Yes	Yes	No	Yes
1.2	The assignment of subjects to treatment groups is randomised.	Yes	Yes	Yes	Yes
1.3	An adequate concealment method is used.	No	Can't say	No	Can't say
1.4	The design keeps subjects and investigators 'blind' about treatment allocation.	No	No	No	No
1.5	The treatment and control groups are similar at the start of the trial.	Yes	Yes	Can't say	Can't say
1.6	The only difference between groups is the treatment under investigation.	Yes	Yes	Yes	Can't say
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	Yes	Yes	Yes	Yes
1.9	All the subjects are analysed in the groups to which they were randomly allocated.	Yes	Yes	Yes	Yes
1.10	Where the study is carried out at more than one site, results are comparable for all sites.	N/A	N/A	N/A	N/A
2.1	How well was the study done to minimise bias?	+	+	-	-
2.2	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes	Yes	Yes	Yes

Appendix 4 – Data Extraction table used in this review

Author	Year	Study design	Approach	Steroid	+/- Local Anaesthetic	Outcome Measures	Results	Findings	FUNCTIONAL OUTCOMES: Range of Movement (ROM), Disability, Return To Work (RTW), Quality of Life (QoL), OR other	Safety and Risk	Imaging	Patient	Pathology
Ackerman and Ahmad	2007	RCT	Caudal, transforaminal or interlaminar	Triamcinolone	Lignocaine	Oswestry Low Back Pain Scale and Beck depression score	By the 12 and 24 week evaluation periods, the transforaminal technique had significantly more patients reporting complete or partial pain relief. Pain scores improved within groups but were also significantly lower with the transforaminal approach.	The transforaminal route of epidural steroid placement is more effective than the interlaminar or caudal routes. We attribute this observation to a higher incidence of steroid placement in the ventral epidural space when the transforaminal method is used.	Function and depression scores improved within groups but did not differ among techniques.	No patient in this study had an infection, headache, intravascular injection, a reaction to the contrast material or a subarachnoid injection.	Fluoroscopy	90 patients aged 18-60 years	Lumbar disc herniation
Barre et al	2004	Retrospective chart review with questionnaire follow up	Caudal	Triamcinolone	Lignocaine	Verbal Numeric Pain Scale (VNS), North American Spine Society (NASS) Patient Satisfaction Index, Roland-Morris Disability Questionnaire (RMDQ)	Pain: 50% improved by 2 points or more at follow-up; with 35% reporting at least a 50% improvement. 42% of patients found the procedure fully met their expectations or would undergo the procedure again for the same outcome.	Caudally placed fluoroscopically guided epidural steroid injections offered a safe, minimally invasive option for managing pain caused by lumbar spinal stenosis.	RMDQ improved by 2 points or greater in 36% of patients	There were no reported major complications such as infection, dural tear, or nerve injury following any procedures.	Fluoroscopy	80 patients aged 40-91 years	Spinal stenosis
Dashfield et al	2005	RCT	Caudal vs targeted steroid placement (spinal endoscopy)	Triamcinolone	Lignocaine	Short Form McGill Pain Questionnaire (SF-MPQ), Anxiety and depression Scale (HADS)	Both groups improved, however there were no significant differences between groups for any measures at any of the time points.	The targeted placement of epidural steroid onto the affected nerve root causing sciatica does not significantly reduce pain intensity and anxiety and depression compared to untargeted caudal epidural steroid injection. Both techniques benefited patients	Anxiety and depression improved in both groups, the difference between groups was not statistically significant.	Non-persistent post-procedure low back discomfort in all epiduroscopy patients, and fewer caudal patients. No patients reported infection or post-spinal headache	Fluoroscopy	60 patients aged 24-84 years	Sciatica
Datta and Upadhyay	2011	RCT	Caudal	Methylprednisolone vs Triamcinolone vs dexamethasone	Bupivacaine	Pain visual analogue scale (VAS), Roland Morris low-back-pain disability questionnaire, straight leg raise and finger to floor distance	All 4 groups showed a significant improvement from baseline by 3 weeks. The steroid groups continued complete or partial pain relief until 6 weeks with the difference between groups not statistically significant by week 12. A significant number of patients in the dexamethasone group required a 3rd injection to achieve pain relief. In the bupivacaine group only 15% of the patients had pain relief at the end of 6 weeks and more than half had recurrent pain at subsequent follow up.	Short term improvement in leg pain and sensory deficits was observed in patients with sciatica due to a herniated nucleus pulposus with both epidural bupivacaine and steroids. All long-acting steroids had no statistically significant difference between their efficacy in pain relief but methylprednisolone and triamcinolone were more effective by the second injection as compared to dexamethasone.	The methylprednisolone group had greater improvement in the finger-to-floor distance compared to the other steroid groups.	No patients complained of backache following the caudal injection. 13.49% of patients complained of pain at injection site. 4.9% of patients complained of tinnitus and 1 decreased hearing. 32.5% patients complained of headache after injection. Mild nausea was reported in 28 patients but no vomiting or dizziness. No incidence of epidural haematoma, intravascular injection, nerve root injury, subarachnoid injection or meningitis was reported in any patients.	None	207 patients aged 27-70 years	Sciatica
Galhom and Al-Shatouri	2013	RCT	Transforaminal vs caudal	Triamcinolone acetonide	Bupivacaine	Pain during injection, immediate pain relief and complications	Caudal epidural injections were beneficial in 5 out of 9 cases and transforaminal 22 out of 28 cases	Fluoroscopy guided lumbar spine injections significantly reduced both back and radicular pain and improved disability in patients with symptomatic discogenic and degenerative lumbar spinal disease. Transforaminal epidural injections were beneficial for more patients than caudal	Not reported	80% of procedures did not show any complications. Temporary weakness for 1 day was noticed in 6 cases after transforaminal epidural injection.	Fluoroscopy	60 patients aged 22-70 years	Chronic low back pain

Author	Year	Study design	Approach	Steroid	+/- Local Anaesthetic	Outcome Measures	Results	Findings	FUNCTIONAL OUTCOMES: Range of Movement (ROM), Disability, Return To Work (RTW), Quality of Life (QoL), OR other	Safety and Risk	Imaging	Patient	Pathology
Iversen et al	2011	Double blind, prospective RCT	Caudal vs saline	Triamcinolone acetonide	None	Oswestry disability index scores, European quality of life measure, Visual analogue scale	All groups improved after the interventions, but we found no statistical or clinical differences between groups over time.	Caudal epidural steroid or saline injections are not recommended for chronic lumbar radiculopathy	No difference between groups	Not reported	None	133 patients aged mean 41.9 years	Lumbar radiculopathy
Kamble et al.	2016	RCT	Caudal vs transforaminal vs interlaminer	Triamcinolone	Bupivacaine	Pain visual analogue scale (VAS), Oswestry Disability Index (OSD)	The change in pain scores was statistically different at 1- and 6-months in the transforaminal compared to the other 2 routes.	In the current study, transforaminal steroid injection group has better symptomatic improvement for both short and long term as compared to interlaminar and caudal steroid injection group.	A greater change was observed in the OSD in the transforaminal at all time points compared to the other 2 routes.	Not reported	Fluoroscopy	90 patients	Prolapsed disc
Karamouzian et al.	2014	RCT	Caudal vs transforaminal	Methylprednisolone acetate	Bupivacaine and lignocaine	Prolo scale, walking and standing tolerance tests, rest days due to back pain	The degrees of pain reduction in the caudal injection group in the 2nd and 6th months were 0.6 and 1.63, respectively, and in the transforaminal injection group were 1.33 and 1.56, respectively. The difference between the 2 methods was not statistically significant.	In the current study, the caudal and transforaminal steroid injection methods showed similar outcomes in the treatment of relapsed lumbar disc herniation.	No statistically significant differences between groups	Not reported	None	32 patients aged 47.8 years (mean)	Lumbar disc herniation
Lee et al.	2009	Retrospective chart review	Caudal vs transforaminal vs interlaminer	Triamcinolone	Lignocaine	Visual Analogue scale (VAS) pain score, patient satisfaction index (PSI), Roland 5-point pain score	Higher ratio of successful results were found in translaminar and transforaminal techniques than caudal. Transforaminal groups showed more reduction of Roland score than caudal approach.	Translaminar and transforaminal approach were more effective than the caudal approach. Especially, effectiveness of transforaminal approach was more prominent in the spinal stenosis group compared to the herniated disc group.	Not reported	Not reported	Fluoroscopy	233 patients aged 40-60 years	Herniated disc or spinal stenosis
Lee et al	2010	Retrospective chart review	Caudal	Triamcinolone acetate	Bupivacaine hydrochloride	5-point patient satisfaction scale	Initial follow up (after average 18.4 days) improvement on the satisfaction scale was seen in 185 patients (85.6%). Excellent improvement (including much improved, no pain) was seen in 103 patients (47.7%).	Fluoroscopically guided caudal epidural steroid injection was effective for the management of degenerative lumbar spinal stenosis (especially central canal stenosis) with excellent short-term and good long-term results, without significant outcome predictors.	Not reported	Not reported	Fluoroscopy	216 patients aged 48-91 years	Degenerative spinal stenosis
Makki et al.	2010	RCT	Caudal	Methylprednisolone	Bupivacaine	Verbal Pain Score (VPS, 1-10), Oswestry Disability Index (ODI)	In group 1 (active), 26 patients (93%) showed improvement in VPS, 2 patients (7%) remained unchanged. In group 2 (control), 23 patients (77%) showed improvement in VPS, 4 patients (14%) remained unchanged, and 2 patients (7%) deteriorated on the VPS. Greater improvement was observed in group 1 compared to group 2.	Laying a patient on the side of their leg pain after a caudal epidural injection has a beneficial effect on the degree of pain relief. We recommend that this simple and safe manoeuvre be introduced routinely after administering a caudal epidural injection, to aid in the eventual outcome of a potentially difficult clinical problem.	The improvement in ODI between the 2 groups was not statistically significant following intention to treat analysis.	No post-operative complications were reported in any case, and all patients were discharged from the day surgery unit on the same day.	Fluoroscopy	57 patients aged (mean (SD)) active: 47 (15), control 49 (9.6)	Herniated disc, spinal stenosis or post laminectomy root adhesions
Manchikanti et al	1999	Retrospective case-control	Transforaminal, interlaminer and caudal	Betamethasone OR methylprednisolone	Lignocaine	> 50% pain relief	TF and Caudal greater than IL at 1-3 months but there was no difference between groups at 3-6 or 6-12 months follow up.	Epidural spinal injection under fluoroscopy by caudal or TF route is a valuable, safe and cost effective technique.	RTW: Economic Analysis	Not reported	Blind interlaminar vs fluoroscopic guided caudal/ transforaminal injections	Unclear	Low back and leg pain
Manchikanti et al	2012 & 2008	RCT	Caudal	Betamethasone	+	NRS pain scale (0-10), ODI pain scale (0-50), employment status, medication use.	Overall, significant pain relief and functional status improvement (≥ 50%) were demonstrated in 48% in control (no steroid) and 46% in the active (with steroid). However, significant pain relief and functional status improvement were seen in 60% of the participants in both groups in the successful category when participants were separated into successful and failed categories.	Caudal epidural injections of local anaesthetic with or without steroids may be an effective treatment for a select group of patients with chronic function-limiting low back and lower extremity pain secondary to spinal stenosis.	ODI functional assessment: At 12 months, 50% in both groups showed significant improvement. No change was observed in employment status from baseline to 12 months.	No participants reported significant adverse events during the study period.	Fluoroscopy	100 participants aged (mean) 56.9 (no steroid group), 55.7 (with steroid group)	Spinal stenosis

Author	Year	Study design	Approach	Steroid	+/- Local Anaesthetic	Outcome Measures	Results	Findings	FUNCTIONAL OUTCOMES: Range of Movement (ROM), Disability, Return To Work (RTW), Quality of Life (QoL), OR other	Safety and Risk	Imaging	Patient	Pathology
Manchikanti et al	2011 & 2008	RCT	Caudal	Betamethasone OR methylprednisolone	Lignocaine	NRS pain scale (0-10), ODI pain scale (0-50), employment status, medication use.	The percentage of patients with significant pain relief of 50% of greater and/or improvement in functional status with 50% or more reduction in ODI scores was seen in 70% and 67% in group 1 (no steroid) and 77% and 75% in group 2 (with steroid). However, the relief with first and second procedures was significantly higher in the steroid group.	Caudal epidural injection with local anaesthetic with or without steroids might be effective in patients with disc herniation or radiculitis. The present evidence illustrates potential superiority of steroids compared with local anaesthetic at 1 year follow up.	There was a statistically significant difference in ODI score between groups at 3 months but not at 6 or 12 months. There was no significant difference in employment characteristics following the intervention at any point.	There were no major adverse events reported over a period of 1 year in all 120 patients.	Fluoroscopy	120 patients aged (mean) 48.7 (no steroid group), 43.0 (with steroid group)	Lumbar disc herniation and radiculitis
Manchikanti et al.	2011 & 2008	RCT	Caudal	Betamethasone OR methylprednisolone	Lignocaine	NRS pain scale (0-10), ODI pain scale (0-50), employment status, medication use.	Significant pain relief and functional status improvement were observed in 55% of group 1 (without steroid) and 68% of group 2 (with steroids).	Caudal epidural injections with local anaesthetic with or without steroids are effective in patients with chronic low back pain of discogenic origin without facet joint pain, disc herniation, and/or radiculitis.	At 12 months, 55% in group 1 (without steroid) and 72% in group 2 (with steroid) showed significant improvement in the ODI. There were no differences between groups in employment characteristics at 12 months.	No participants reported significant adverse effects during the study period.	Fluoroscopy	120 patients aged (mean) 48.5 (no steroid group), 43.9 (with steroid group)	Chronic discogenic low back pain without disc herniation or radiculitis
Manchikanti et al.	2010 & 2008	RCT	Caudal	Betamethasone	Lignocaine	NRS pain scale (0-10), ODI pain scale (0-50), employment status, medication use.	Combined pain relief (≥50%) and disability reduction was recorded in 53% of patients in the local anaesthetic group and 59% of patients in the local anaesthetic and steroid group with no significant differences noted with or without steroid over a period of one year.	Caudal epidural injections in chronic function-limiting low back pain in post-surgery syndrome without facet joint pain may be effective in a significant proportion of patients with improvement in functional status and significant pain relief.	Significant improvement of functional status was seen in both groups from baseline to one-year on ODI score. Reduction of Oswestry scores of at least 50% was seen in 56% (without steroid) and 61% (with steroid) of participants. There was no significant difference in employment characteristics following the intervention at any point.	No major adverse events were reported over the one-year study period in any of the 140 participants.	Fluoroscopy	140 patients aged (mean) 52.4 (no steroid group), 48.0 (with steroid group)	Post lumbar surgery syndrome
Manchikanti et al.	2013	Economic study	Caudal	Betamethasone OR methylprednisolone	Lignocaine	Reimbursement data (payments for physician assessment for each visit, facility expenses).	The results of the 4 RCTs of low back pain with 480 patients with a 2-year follow-up with the actual reimbursement data showed cost utility for one year of QALY of $2,206 for disc herniation, $2,136 for axial or discogenic pain without disc herniation, $2,155 for central spinal stenosis, and $2,191 for post-surgery syndrome.	The cost utility analysis of caudal epidural injections in the treatment of disc herniation, axial or discogenic low back pain, central stenosis, and post surgery syndrome in the lumbar spine shows the clinical effectiveness and cost utility of these injection at less than $2,200 per one year of QALY.	Not reported	Not reported	Fluoroscopy	480 patients	Disc herniation, discogenic low back pain, spinal stenosis, post surgery syndrome
Manchikanti et al	2015	RCT	Caudal vs interlaminar vs transforaminal	Betamethasone OR methylprednisolone	Lignocaine	NRS pain scale (0-10), ODI pain scale (0-50), employment status, medication use.	Pain relief and functional assessment: No significant difference between groups. A similar proportion in all groups improved.	In the present study comparing caudal, interlaminar, and transforaminal approaches to epidural injections in 3 large trials of 120 patients in each trial receiving either local anaesthetic alone or local anaesthetic with steroid showed a lack of superiority for any of the approaches.	No significant differences between groups	There were no major adverse events in any of the 3 trials	Fluoroscopy	360 patients	Lumbar disc herniation
McCahon et al	2011	RCT	Caudal	Methylprednisolone	Bupivacaine	Oswestry disability Index (ODI), medication use	No statistically significant change in medication use was found from week to week in either group.	Methylprednisolone acetate 40mg appears to be as effective as 80mg in improving disability associated with chronic low back pain, and should be considered in preference of 80mg dose for outpatients with chronic low pain attending for repeat steroid injections.	ODI improved in both groups (high and low dose) over time following injection, but a statistically significant improvement only occurred in the 40mg dosage group not in the 80mg group.	There were no adverse events reported by participants during the study.	None	33 participants	Low back low pain

Author	Year	Study design	Approach	Steroid	+/- Local Anaesthetic	Outcome Measures	Results	Findings	FUNCTIONAL OUTCOMES: Range of Movement (ROM), Disability, Return To Work (RTW), Quality of Life (QoL), OR other	Safety and Risk	Imaging	Patient	Pathology
Mendoza-Lattes et al	2009	Retrospective case-control	Caudal vs Transforaminal	Methylprednisolone or betamethasone	Bupivacaine in TF group only	Visual Analogue Scale (VAS), ODI, SF-36	Symptom improvement was comparable between both treatment groups.	The effectiveness of caudal and transforaminal epidural steroid injections for the treatment of primary lumbar radiculopathy were compared in a retrospective case control study. They were found to be equivalent, and allowed patients to decline surgery in approximately 60% of cases.	SF-36 improved to 42.0 ± 11.8 and 37.7 ± 12.3, respectively (p=0.49). ODI improved from 50.0 ± 21.2 to 15.6 ± 17.9 and from 62.1 ± 17.9 to 26.1 ± 20.3, respectively (p=0.407).	Not reported	Fluoroscopy	132 patients	Lumbar radiculopathy
Murakibhavi and Khemka	2011	RCT	Caudal	Triamcinolone	Lignocaine	Visual Analogue Scale (VAS), ODI, Beck depression inventory, numerical pain intensity questionnaire	The intervention group had a larger number of patients who reported complete pain relief even at the end of the 6 month evaluation period.	Caudal epidural steroid injections seem to be effective when treating patients with low back pain and sciatica. They are easy to perform, less technically demanding, and with low complications compared with conservative treatment. Caudal epidural injections may offer an interesting alternative approach to managing low back pain and sciatica.	ODI scores were significantly improved within the intervention group. The patients' mean scores kept decreasing al all follow-up re-evaluations. Beck depression inventory scores, VAS and NPI score improved within the group.	Complications seen with the procedure included technical difficulties associated with passing the sacrococygeal ligament, also dural puncture and headaches.	None	102 patients mean age 44.64 (SD:12.65)	Low back pain and sciatica
Pandey	2016	RCT	Caudal vs interlaminar vs transforaminal	Methylprednisolone	Lignocaine	Japanese Orthopaedic Association (JOA) Score	At one year after injecting the steroid, all three routes were found to be effective in improving the JOA score (Caudal route in 74.3%, transforaminal 90% and interlaminar in 77.7%). Transforaminal route was significantly more effective than caudal (p=0.00) and interlaminar route (p=0.03) at both 6 months and one year after injection. No significant difference was seen between the caudal and interlaminar route (p=0.36).	The management of low back pain and radicular pain due to a prolapsed lumbar intervertebral disc by injecting methyl prednisolone in epidural space is satisfactory in the current study. All 3 injection techniques are effective with the best result obtained by transforaminal route.	Not reported	In the current study, 15 patients from the caudal group complained of sweating and transient drowsiness during the time of injection. Post injection hypotension was recorded in all these patients. None of the patients in the group had an infection, headache or reaction to contrast material and medication used. There was no incidence of an intravascular or a subarachnoid injection.	Fluoroscopy	152 patients	Lumbar prolapsed intervertebral disc
Park et al.	2013	RCT	Caudal	Dexamethasone	Lignocaine	Verbal numerical rating scale (VNS), 5-point satisfaction scale, contrast pattern, ODI	The VNR scale and the ODI improved 2 and 12 weeks after the injections in both groups. Statistical differences were not observed in the VNR scale, ODI or the effectiveness of the procedure between groups. Two cases of intravascular injections were observed in the fluoroscopy group, without the prevalence of complication between the groups.	The ultrasound approach with colour Doppler mode may avoid intravascular injection-induced complications. The results showed similar improvements in short-term pain relief, function, and patient satisfaction with both ultra-sound and fluoroscopic guidance.	No difference between groups in any of the functional outcomes	Immediately after the procedure, 2 patients in the US group and 1 in the FL group had a transient headache (P>0.05). Overall, among the injected patients, 5 in the US group and 4 in the FL group reported transient pain exacerbation 48 hours after the procedure during the 2 week follow up session. No patients reported any headaches suggestive of post lumbar puncture syndrome or decompensated heart disease or diabetes.	Ultrasound vs Fluoroscopy	120 patients mean ultrasound guided: 57.27 ± 10.11, 58.47 ± 9.22	Lower lumbar radicular pain

Author	Year	Study design	Approach	Steroid	+/- Local Anaesthetic	Outcome Measures	Results	Findings	FUNCTIONAL OUTCOMES: Range of Movement (ROM), Disability, Return To Work (RTW), Quality of Life (QoL), OR other	Safety and Risk	Imaging	Patient	Pathology
Ploumis et al.	2014	RCT	Caudal vs transforaminal	Betamethasone	Lignocaine	VAS for leg pain, ODI	A significantly greater number of stenosis patients showed pain relief at 6 months post injection with Transforaminal (90%) than with caudal (54.54%). All patients with transforaminal showed improvement of function at 6 months while only 3 (27.27%) patients with caudal epidural improved functionally.	The effectiveness of transforaminal steroid injection for the stenosis patients with sciatica was superior to caudal at 6 months post injection.	At 6 months post injection, all 20 patients (100%) in the transforaminal group had substantially improved function (at least 15 degrees reduction of ODI) while only 3 of 11 patients (27.27%) in caudal group improved.	No major complications were seen following the injections. Minor complications included vagal reactions in four patients (two in each group) before the start of the procedure, which necessitated rescheduling to another day.	None	40 patients mean (SD) age caudal: 67.2 (3.0), transforaminal 64.7 (1.8)	Spinal stenosis with sciatica
Revel et al	1996	RCT	Caudal	Prednisolone	+	Work status, sick leave, surgical procedure, severity of pain,Waddell's and Main's functional score, Schober's test, finger-to-floor distance, straight leg test, medication use, patient satisfaction	After 6 months, the proportion of patients who were relieved of their sciatica was significantly higher in the forceful injection group (45%) than in the control group (19%), p=0.03. Nerve root pain evaluated on a VAS and by Schober's index showed significantly greater improvement in the forceful injection group than in the control group. After 18 months, results were still in favour of the forceful injection group, with success rates of 39% for the sciatica and 31% for low back pain.	Although mediocre overall, the results of forceful epidural corticosteroid injections are better than those of simple epidural injections of a corticosteroid alone. Given the paucity of effective treatments for lumbosciatic pain apparently due to postoperative fibrosis, forceful injections should be given a place in the treatment of this condition.	No difference between groups	No complications were recorded during the study. The most common adverse event was lumbar pain radiating along the path of the nerve root pain or down the opposite lower limb during the injection. Among drop-outs, 4 in the forceful injection group and 1 in the control group gave intolerable pain as the reason for their decision to leave the study.	None	60 patients aged mean 42 years	Lumbosciatic pain with post-operative lumbar spinal fibrosis
Southern et al	2003	Retrospective	Caudal	Betamethasone	Lignocaine	VNS	Only 19 patients (23%) were determined to have a successful long term (> 1 year) outcome and 65 (77%) were deemed failures. Successes were found to differ significantly from failures in pre-injection pain scores and patient satisfaction. Overall patient satisfaction was 45%.	At greater than 2-year follow-up, the efficacy of fluoroscopically guided caudal epidural steroid injections in patients with chronic lumbar discogenic pain is poor. Patient satisfaction exceeds the reported rate of efficacy.	Not reported	Not reported	Fluoroscopy	97 patients	Chronic low back pain
Yousef et al	2010	RCT	Caudal	Methylprednisolone	Bupicavaine	Verbal pain scale, spine mobility, medication use	Significant improvement in short-term pain relief was noted in both groups, while significant long-term pain relief was only achieved in group 2 (hyaluronidase).	The addition of hyaluronidase to fluoroscopically guided caudal epidural steroid and hypertonic saline combination improved long-term pain relief in patients with failed back surgery syndrome.	Significant improvement in the range of motion of the lumbar spine flexion, extension, and lateral flexion occurred in group 2 patients during follow up period 1 year after treatment, while significant improvement in group 1 patients occurred only up to 3 months after treatment.	Minor complications, such as rash and itching, occurred in patients who received hyaluronidase, although not statistically significant, and this could be explained by its potential for allergic reaction. There were no instances of sub-arachnoid blockade or infection. None of the patients suffered from paralysis, weakness, bladder disturbances, or other serious complications.	Fluoroscopy	38 patients mean age (SD) group 1: 48.8 (3.63), group 2: 49.1 (3.88)	Failed back surgery syndrome