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Comparative effectiveness and safety of varying corticosteroid doses for lumbar epidural steroid injections: a protocol for a systematic review and narrative synthesis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - None.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 5 November 2025 and was last updated on 5 November 2025.

INTRODUCTION

Review question / Objective The objective of this systematic review is to compare the effectiveness and safety of varying corticosteroid doses administered via lumbar epidural steroid injections (ESIs) in patients with lumbar spine–related pain. Accordingly, this review will address the following research question: “Among adults receiving lumbar ESIs for lumbar spine–related pain, what is the minimum effective corticosteroid dose while minimizing the likelihood of treatment-related complications?”.

Rationale

The clinical outcomes and potential adverse effects of corticosteroids given through lumbar ESIs are influenced by multiple factors, such as route of administration, injectate volume, and type of corticosteroids. Dosages of corticosteroid in lumbar ESIs also represent one of the important parameters. However, to the best of our knowledge, no systematic review to date has specifically evaluated the comparative effectiveness and safety of different corticosteroid doses used in lumbar ESI. Given that corticosteroid-related adverse events are dose dependent,(1) the absence of systematic reviews on optimal dosing represents a significant gap in current clinical practice. It may contribute to differences in practice patterns, placing patients at risk of receiving less effective or unsafe treatment regimens.

Therefore, a systematic review focusing on the comparative effectiveness and safety of varying corticosteroid doses used in lumbar ESI is urgently needed. This review aims to determine the lowest effective dose of corticosteroid that achieves therapeutic benefit while minimizing the likelihood of adverse effects.

Condition being studied

Lumbar ESI is a widely utilized interventional procedure for the management of chronic low back pain. Through anti-inflammatory action, corticosteroids relieve pain and promote functional improvement.(1) However, corticosteroids are also associated with a range of local and systemic

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adverse effects that are known to be dose-dependent.(2) Therefore, determining the optimal corticosteroid dose is critical to achieving therapeutic benefits while minimizing risks.

METHODS

Search strategy

A comprehensive search strategy will be implemented to identify all relevant studies assessing the effectiveness and safety of different corticosteroid doses in lumbar ESI. Three electronic databases—PubMed, Embase, and Web of Science—will be systematically searched from inception to August 12, 2025. Searches will be limited to articles published in English and conducted with human participants.

The strategy will combine free-text keywords covering three main concepts: 1. terms describing the injection techniques, such as epidural, transforaminal, caudal, or interlaminar injections; 2. corticosteroid agents, such as dexamethasone (DXM), methylprednisolone (MP), triamcinolone (TA), and betamethasone (BMZ); and 3. dose-related expressions, such as low dose, optimal dose, dosage, and dosing.

Boolean operators (e.g., AND, OR) and truncation symbols will be used to combine terms appropriately. Each database search will be adapted to its specific indexing system and syntax requirements. The overall approach aims for high sensitivity and reproducibility, ensuring comprehensive retrieval of eligible studies for inclusion in this systematic review.

Participant or population

This review will include adult patients (aged ≥18 years) who received lumbar ESIs. There will be no restrictions based on sex, ethnicity, or geographic region.

Intervention

The intervention of interest in this review is lumbar ESIs administered with different corticosteroid doses of the same corticosteroid agent (e.g., DXM, MP, TA, BMZ), regardless of the injection approach (interlaminar, transforaminal, or caudal) or the corticosteroid formulation (particulate or non-particulate).

Comparator

The comparator will consist of lumbar ESIs performed with different corticosteroid doses of the same corticosteroid agent (e.g., DXM, MP, TA, BMZ).

Study designs to be included

This review will include randomized controlled trials (RCTs) and comparative observational studies. Case reports, case series, reviews, editorials, conference abstracts, and other non-original studies will be excluded.

Eligibility criteria

Eligibility criteria for this review will be defined according to the PICOS framework to ensure that the research question is appropriately addressed.

Studies will be included if they meet the following conditions:

- Population: Adults aged 18 years or older receive lumbar ESIs.
- Intervention and Comparator: Lumbar ESIs administered using different dosages of the same corticosteroid preparation regardless of the injection approach (interlaminar, transforaminal, or caudal) or corticosteroid formulation (particulate or non-particulate).
- Outcomes: Studies reporting clinical effectiveness (e.g., pain relief, functional improvement) and/or adverse effects.
- Study design: Comparative observational studies or RCTs.

Eligible studies will be limited to peer-reviewed, full-text articles written in English. Studies will be excluded if they are (1) non-original works such as case reports, case series, reviews, editorials, conference abstracts; (2) animal-based investigations; or (3) lacking sufficient data on the predefined outcomes. No restrictions will be applied regarding publication year or country.

Information sources

A comprehensive literature search will be conducted across multiple electronic databases to identify all relevant studies evaluating the effectiveness and safety of different corticosteroid doses in lumbar ESIs. The primary databases to be searched include PubMed, Embase, and Web of Science. All searches will be restricted to studies published in English and conducted in human participants, with no limitations on publication year or geographic region. The detailed search strategy used for each database is described in the section Search strategy to ensure methodological transparency and reproducibility.

Main outcome(s)

The primary outcomes of this review will include measures of clinical effectiveness and/or safety associated with different corticosteroid doses in lumbar ESIs. Effectiveness outcomes can include pain reduction and functional improvement, although other clinically relevant indicators of

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therapeutic benefit will also be considered. Safety outcomes will include adverse events.

Additional outcome(s)
No additional outcomes are planned.

Data management
All search results were imported into EndNote X. Two reviewers will select included studies based on predefined eligibility criteria. Data extraction was independently conducted by two reviewers. Any discrepancies were resolved through discussion, and when consensus could not be reached, a third author was consulted.

Quality assessment / Risk of bias analysis
Randomized controlled trials were appraised with the Revised Cochrane Risk of Bias Tool (RoB 2),(3) and non-randomized studies with the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I).(4)
For RCTs, RoB 2 examined five domains related to randomization, deviations from intended interventions, missing outcome data, outcome measurement, and selective reporting. Each domain was rated as low risk, some concerns, or high risk, with the overall rating determined by the most critical judgment. For crossover trials, an additional assessment for period and carryover effects was included.
For non-randomized designs, ROBINS-I evaluated seven domains, including confounding, participant selection, intervention classification, deviations from intended treatment, missing data, outcome measurement, and selective reporting. The risk of bias was categorized as low, moderate, serious, critical, or no information, with the overall rating based on the highest level of bias observed.

Strategy of data synthesis
Given the expected heterogeneity in study designs, interventions, and outcome measures, a narrative synthesis will be conducted. Findings will be analyzed in terms of both the effectiveness and safety of different corticosteroid doses. Within each of these domains, studies will be grouped according to the type of corticosteroid (DXM, MP, TA, BMZ) and evaluated for their respective therapeutic and safety outcomes. General trends describing the relationship between dose and treatment effect or adverse events will be identified, with particular emphasis on determining the lowest effective dose that achieves therapeutic benefit while minimizing the risk of side effects.

Subgroup analysis
No subgroup analysis is planned, as the review will employ a narrative synthesis without quantitative pooling.

Sensitivity analysis
No subgroup analysis is planned, as the review will employ a narrative synthesis without quantitative pooling.

Language restriction
The search will be restricted to studies published in English. Non-English publications will be excluded from this review.

Country(ies) involved
This review is conducted collaboratively by researchers from South Korea and Canada.

Contributionship: All authors contributed equally to this work.

Keywords
Epidural; Corticosteroid; Optimal dose; Adverse Effects.

Dissemination plans
We plan to publish the results in a peer-reviewed journal.

Contributions of each author
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