INPLASY PROTOCOL

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Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

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The authors declared no potential conflicts of interest.

Hip fracture risk with corticosterioids in patients with COPD: a systematic review and meta-analysis

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Review question / Objective: **To evaluate the association between the risk of hip fracture and corticosteroids in patients with COPD. The risk is compared with patients without COPD. Included studies were RCTs and observational studies.**
Condition being studied: **Chronic obstructive pulmonary disease (COPD) is a complex respiratory disease characterized by the progressive limitation of the airflow and the abnormality of the inflammatory response of the airways. The disease remains serious health problems around the world. COPD patients treated with glucocorticoids have an increased risk of osteoporosis and fragility fractures. Glucocorticosteroids, is prescribed in patients with COPD for their anti-inflammatory effect.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 April 2020 and was last updated on 16 April 2020 (registration number INPLASY202040098).

INTRODUCTION

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osteoporosis and fragility fractures. Glucocorticosteroids, is prescribed in patients with COPD for their anti-inflammatory effect.

METHODS

Participant or population: Patients diagnosed COPD.

Intervention: The experiment group were treated with different kind of corticosteroids including oral corticosteroids, inhaled corticosteroids.

Comparator: Patients without COPD.

Study designs to be included: Randomized controlled trials (RCTs) and observational studies (case-control, prospective cohort or retrospective cohort).

Eligibility criteria: Our inclusion criteria were: (1) Randomized controlled trials, and observational studies were included. (2) Patients diagnosed COPD according to the guideline. (3) Both oral and inhaled coricorsteriods as intervention. (4) Outcome data on hip fractures. Exclusion criteria: Studies did not report hip fractures on both experiment group and control group were excluded.

Information sources: PubMed, Embase and Cochrane Library databases were searched to identify randomized controlled trials (RCTs) and observational studies (case-control, prospective cohort or retrospective cohort) reporting on the hip fractures among patients with COPD. In addition, the reference lists of the articles were also reviewed manually to detect other potentially appropriate publications.

Main outcome(s): Outcome of hip fractures in both experiment group and control group.

Quality assessment / Risk of bias analysis: The quality of RCTs will be assessed by 2 authors using the tools introduced from the Cochrane Handbook. 8 domains will be assessed according to the Cochrane Handbook: random sequence generation; allocation concealment; blinding of participants; blinding of personnel; blinding of outcome assessment; incomplete outcome data; selective reporting; other biases (baseline imbalance, the similarity in using cointerventions between groups, and inadequate statistical analysis). Newcastle Ottawa Scale will be used to assess the quality of observational studies. With an overall quality score ranging from 0 to 9, the selection was assigned for 4 scores, comparability for 2 scores and outcomes for 3 scores. 0-3 scores were considered as low quality, 4-6 was deemed as moderate quality and over 6 scores were determined as high quality. The dispute will be solved by a third author.

Strategy of data synthesis: The main outcome in this meta-analysis is the number of hip fractures among patients with COPD using glucocorticoids. Pooled data will be calculated as an OR with 95% CIs. Forest plots will be created showing a summary of results with 95% CIs. I2 analyses were used to assess heterogeneity between studies, I2 >50% indicated a significant heterogeneity. The fixed effect (FE) model will be first used, and if the I2>50% which indicates the substantial level of heterogeneity, the random effect (RE) model was chosen. Publication bias will be shown visually using funnel plots. Review Manager 5.3 (Cochrane IMS, Copenhagen, Denmark) will be used to analyze the data and generate a frost plot. Sensitivity analyses will be made by excluding studies serially and assess its effect on the overall results. Publication bias will be evaluated visually using funnel plots.

Subgroup analysis: To detect potential causes of heterogeneity, we will conduct subgroup analyses based on the different corticosteroids used in treating COPD.

Sensibility analysis: Sensitivity analyses will be made by excluding studies serially and assess its effect on the overall results.

Country(ies) involved: China.

Keywords: Hip fractures; chronic obstructive pulmonary disease; corticosteroids; COPD.

Contributions of each author:

Author 1 - Retrieval of literature, screening of the literature; data extraction; the data analysis; manuscript drafting.
Author 2 - Retrieval of literature, screening of the literature; data extraction; the data analysis.
Author 3 - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - The author provided statistical expertise.