INPLASY PROTOCOL

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Corresponding author:
Xue Yang

xantheyoung@126.com

Author Affiliation:
Peking University First Hospital

Support: **None.**

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Conflicts of interest: **None.**

Venous thromboembolism in patients with Coronavirus Disease 2019 (COVID-19): a systematic review and meta-analysis

Yang X[1]; Zhang, X[2]

Review question / Objective: **This meta-analysis aimed to explore venous thromboembolism on severity differences and mortality in patients with COVID-19. P: patients with Coronavirus Disease 2019(COVID-19); E: mild to moderate patients; C:severe patients; O:venous thromboembolism.**
Condition being studied: **It has been postulated that the high mortality observed among COVID-19 patients may be partly due to unrecognized pulmonary embolism (PE) and pulmonary in situ thrombosis. Estimates of the risk of arterial and, in particular, venous thromboembolic complications are still preliminary and depend on local diagnostic and pharmacological preventive strategies. Better understanding of COVID-19-related thromboembolic risk will help to optimize diagnostic strategies and guide the design and conduction of randomized controlled trials on VTE prevention. In this article, we try to explore venous thromboembolism on severity differences and mortality in patients with COVID-19.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 May 2020 and was last updated on 07 May 2020 (registration number INPLASY202050024).

INTRODUCTION

Review question / Objective: **This meta-analysis aimed to explore venous thromboembolism on severity differences and mortality in patients with COVID-19. P: patients with Coronavirus Disease 2019(COVID-19); E: mild to moderate patients; C:severe patients; O:venous thromboembolism.**

Rationale: **COVID-19 is associated with coagulopathy and a significant increased risk of thrombotic events. This meta-analysis aimed to explore venous thromboembolism on severity differences and mortality in patients with COVID-19.**

Condition being studied: It has been postulated that the high mortality observed among COVID-19 patients may be partly due to unrecognized pulmonary embolism (PE) and pulmonary in situ thrombosis. Estimates of the risk of arterial and, in particular, venous thromboembolic complications are still preliminary and depend on local diagnostic and pharmacological preventive strategies. Better understanding of COVID-19-related thromboembolic risk will help to optimize diagnostic strategies and guide the design and conduction of randomized controlled trials on VTE prevention. In this article, we try to explore venous thromboembolism on severity differences and mortality in patients with COVID-19.

METHODS

Search strategy: We searched the electronic databased Pubmed, Embase, Cochrane, WanFang Database,CNKI, medRxiv and SSRN from December1,2019 to May 1,2020 using a combination of the following key words: "Covid-19" or "2019 novel coronavirus infection" or "SARS-CoV-2" and "characteristics" or "thromboembolism" .In addition,the references listed in each identified article were also screened and manually searched to make the results more comprehensive.

Participant or population: We included 2000 confirmed COVID-19 infected patients from 20 studies.

Intervention: All patients underwent lower limb vessels ultrasonic examination.

Comparator: Summary relative risks (RRs) with 95% CIs were estimated for the association between VTE and death.

Study designs to be included: Case-control studies, cohort studies and randomized control studies

Eligibility criteria: (1) studies focused on clinical characteristics of patients with COVID-19, including case-control studies, cohort studies and randomized control studies;(2)the patients were divided into mild and severe group, or surviors and non-surviors group; (3)the incidence of VTE between groups were described.

Information sources: We searched the electronic databased Pubmed, Embase, Cochrane, WanFang Database,CNKI, medRxiv and SSRN from December1,2019 to May 1,2020 using a combination of the following key words:"Covid-19" or "2019 novel coronavirus infection" or "SARS-CoV-2" and "characteristics" or "thromboembolism" .

Main outcome(s): Death or admitted to intensive care unit (ICU).

Data management: All statistical analyses were performed on stata14.0(Stata,College Station,TX,USA). For continuous data, we calculated the weighted mean difference(WMD) and the 95%CI. Heterogenity among the studies was assessed by the Chi squared and I2 tests. A random-effects model was used when either P50% defined significant heterogeneity across the articles. Otherwise, the fixed-effects model was used.We also conducted meta-regression to assess whether severity differences in coagulation parameters were modified by patient characteristics: age, sex, smoking and comorbidities. We carried out a sensitivity analysis on the stability of the combined results.Evidence of publication bias was examined using Egger's regression test for funnel asymmetry, in addition to visual inspection of the funnel plots.

Quality assessment / Risk of bias analysis: We used the Newcastle-Ottawa scale (NOS) , which includes patients selection, study comparability and outcomes assessment three components, to evaluate the quality of the original study.

Strategy of data synthesis: Data extraction and the evaluation of literature quality were conducted independently by 2 investigators(Xiaolin Zhang and Xue Yang).Differences were resolved with a

third investigator (Hongmei Jiao) or by consensus.

Subgroup analysis: We also conducted meta-regression to assess whether severity differences in coagulation parameters were modified by patient characteristics: age, sex, smoking and comorbidities.

Sensibility analysis: We carried out a sensitivity analysis on the stability of the combined results.Evidence of publication bias was examined using Egger's regression test for funnel asymmetry, in addition to visual inspection of the funnel plots.

Language: English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Coronavirus,COVID-19, venous thromboembolism.

Contributions of each author:
Author 1 - Xue Yang - XY, XZ, JM and LM designed the study. XY and XZ identified and acquired reports of trials and extracted data. XY and XZ performed all data analyses, checked for statistical inconsistency, and interpreted data. XY and XZ drafted the letter and all other authors critically reviewed the letter.
Author 2 - Xiaolin Zhang - XY, XZ, JM and LM designed the study. XY and XZ identified and acquired reports of trials and extracted data. XY and XZ performed all data analyses, checked for statistical inconsistency, and interpreted data. XY and XZ drafted the letter and all other authors critically reviewed the letter.