INPLASY PROTOCOL

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None declared.

Early versus late tracheostomy in severe stroke-related patients: a systematic review and meta-analysis

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Review question / Objective: **(1) Population: Stroke patients who underwent tracheostomy (2) Intervention: patients with early tracheostomy (3) Control: patients with late tracheostomy (4) Outcomes: the primary efficacy outcome was mortality. The secondary efficacy outcome was Patient prognosis assessed by modified Rankin Scale (mRS), ventilator days, Length of ICU, Length of Hospital Stay and Cost of Hospitalization. Safety outcomes include incidence of complications, incidence of ventilator associated Pneumonia (5) Study type: the study design includes RCTs, high quality cohort studies.**

Condition being studied: **The tracheostomy is a common procedure for ventilated patients in intensive care unit . The optimal timing for tracheostomy in patients with severe stroke is still unclear. This study aimed to investigate the clinical outcomes of early and late tracheostomy in stroke-related patients.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 August 2022 and was last updated on 22 August 2022 (registration number INPLASY202280086).

INTRODUCTION

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METHODS

Participant or population: Stroke patients who underwent tracheostomy because of the need for long-term ventilation were eligible, including stroke patients who had previously undergone tracheostomy.

Intervention: Stroke patients with early tracheostomy were categorized as intervention group.

Comparator: Stroke patients with late tracheostomy were defined as control group.

Study designs to be included: The study design includes RCTs, retrospective studies.

Eligibility criteria: Unpublished studies, review, commentary, conference abstract, letter, or case reports were excluded.

Information sources: Database from PubMed, EMBASE and the Cochrane Library were searched.

Main outcome(s): The primary outcome was mortality.

Additional outcome(s): The secondary efficacy outcome was patient prognosis assessed by modified Rankin Scale (mRS), ventilator days, Length of ICU, Length of Hospital Stay and Cost of Hospitalization.

Quality assessment / Risk of bias analysis: The quality of eligible studies was examined by Newcastle-Ottawa Scale (NOS) ; The risk of bias of RCTs and the nonrandomized studies were evaluated using the Cochrane's Risk of Bias2(RoB2) and the Risk of Bias in Non-Randomized Studies of Interventions (ROBINS-I) tools respectively.

Strategy of data synthesis: Difference estimates for dichotomous and continuous variables were expressed as odds ratios (OR), standardized mean differences (SMD) and mean differences (MD), respectively, and their 95% confidence intervals (CI) were also calculated by Mantel Haenszel statistical method. Heterogeneity of the included studies was assessed by Cochran Q test and the I2 test. In the case of fairly significant heterogeneity (Cochran's Q P < 0.10 or I2 ≥ 50%), a random-effects model was applied, otherwise a fixed-effects model was used P values < 0.05 were considered statistically significant. All the analysis in the study was conducted in R (R version 4.1.3) and Revman (version 5.4).

Subgroup analysis: The included studies were categorized by article type. Besides, the 6 months follow-up mRS score of stroke patients were classified into different subgroup analysis according to different definition of favorable clinical outcome.

Sensitivity analysis: Sensitivity analysis was conducted by subsequently eliminating each study individually to evaluate the quality of the results.

Language restriction: English.

Country(ies) involved: China.

Keywords: stroke, early tracheotomy, mortality, prognosis.

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