INPLASY PROTOCOL

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Support: **National Cheng Kung University.**

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Conflicts of interest:
None declared.

Comparison of the clinical efficacy and safety of standard and ultrasound-assisted thrombolysis for pulmonary embolism

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Review question / Objective: **To compare efficacy and safety of standard and ultrasound-assisted thrombolysis for patients with pulmonary embolism**
Condition being studied: **Patient admitted for pulmonary embolism who received treatment with ultrasound-assisted thrombolysis or standard catheter-directed thrombolysis.**
Eligibility criteria: **All included trials had to include at least 1 USAT treatment arm and 1 SCDT. The target population was adults with acute PE. Single-armed follow-up studies, case series, and case reports are excluded.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 April 2022 and was last updated on 14 April 2022 (registration number INPLASY202240082).

INTRODUCTION

Review question / Objective: **To compare efficacy and safety of standard and ultrasound-assisted thrombolysis for patients with pulmonary embolism.**

Condition being studied: Patient admitted for pulmonary embolism who received treatment with ultrasound-assisted thrombolysis or standard catheter-directed thrombolysis.

METHODS

Participant or population: Patients with pulmonary embolism.

Intervention: Ultrasound-assisted thrombolysis(USAT).

Comparator: Standard Catheter-directed thrombolysis(SCDT).

Study designs to be included: Randomized-controlled trial and observational trials are included.

Eligibility criteria: All included trials had to include at least 1 USAT treatment arm and 1 SCDT. The target population was adults with acute PE. Single-armed follow-up studies, case series, and case reports are excluded.

Information sources: PubMed and Embase database

Main outcome(s): Mortality, PA pressure change post treatment, RV/LV ratio, bleeding

Quality assessment / Risk of bias analysis: All eligible trials were evaluated by 2 reviewers independently using Jadad scoring for RCTs and the Newcastle-Ottawa quality assessment scale for comparative trials.

Strategy of data synthesis: The standardized mean difference (SMD) with a 95% CI was calculated for continuous outcome variables. The odds ratio was calculated for categorical outcome variables, which included the major bleeding event rates and in-hospital mortality and 30-day mortality. A random effects model was used to pool individual SMDs and ORs; all analyses were performed using Comprehensive Meta-Analysis software (version 3; Biostat, Englewood, NJ, USA). Between-trial heterogeneity was determined by using I2 tests, with values >50% considered to indicate significant heterogeneity. Funnel plots and the Egger test were used to determine potential publication bias. Statistical significance was defined as a p value < 0.05; however, for publication bias, p < 0.10 was considered to indicate statistical significance.

Subgroup analysis: Massive pulmonary embolism v.s submassive pulmonary embolism.

Sensitivity analysis: Nil.

Language: English.

Country(ies) involved: Taiwan.

Keywords: pulmonary embolism, ultrasound-assisted thrombolysis, EKOS, catheter-directedt hrombolysis.

Contributions of each author:
Author 1 - Jia-Ling Lin.
Author 2 - I-Yen Chen.
Author 3 - Po-Kai Yang.