Study Protocol and Statistical Analysis Plan

Title: Chemoprophylaxis Plus Early Ambulation Prevent Chinese Thoracic Surgery Patients from Pulmonary Embolism

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Objective: Pulmonary embolism (PE) can be a devastating postoperative complication and the leading cause of mortality after thoracic surgery. PE together with deep venous thrombosis (DVT) is called venous thromboembolism (VTE), whereas PE caused much more serious situation than DVT. For thoracic surgery, American College of Chest Physicians (ACCP) has published prevention guidelines of VTE in non-orthopedic surgical patients and has been used widely, but unfortunately prophylaxis measures had often been underused in China. However, to be honest, there could be a big difference between Chinese and western populations, for example, what guidelines recommended thrombolysis therapy in diagnosed massive or sub-massive PE patients is tissue type plasminogen activator (t-PA) 100 mg, while in China 50 mg has the same effect. The investigators wanted to establish if the prophylaxis measures what they were using currently are suitable for Chinese thoracic surgical patients.

Methods: Single Group Assignment

Early chemoprophylaxis means low-molecular weight heparin (LMWH) 3075 IU (WHO Units) injection subcutaneously QD no later than 24 hours after surgery. Early ambulation means activity out of bed no later than 24 hours after surgery. According to different risk level, patients received different thromboprophylaxis strategies. Early ambulation alone was for patients at low risk (Caprini 0-4), early chemoprophylaxis plus early ambulation was for patients at moderate (Caprini 5-8) or high risk (Caprini ≥9).

Randomization: Open Label

Outcomes:

Major outcome: Incidence of Postoperative Pulmonary Embolism (PE) in Surgical Thoracic Patients Under Currently Used PE Prevention Strategies.

Minor outcome: Provider Adherence in Implementation of PE Prevention Strategies.

Safety outcome: Major bleeding until 2 days after the last intake of injection.

Sample size: 581 cases.

1. Statistical Analysis Plan

Data description: Results were presented as means ± standard deviation (SD). The independent-samples t test was used for continuous variables. The chi-square test and the Fisher's exact test was used for categorical variables. Spearman correlation and multivariable logistic regression was performed for prediction analyses and to explain the relationship between variables.

Missing data: Missing data will be deleted when analyzed.

Statistical value： A P value <0.05 was considered statistically significant.

Statistical software: SPSS 25.0