An Analysis Into the Cause and Preventional Method of Thromboembolic Disease in Gynecological Surgery

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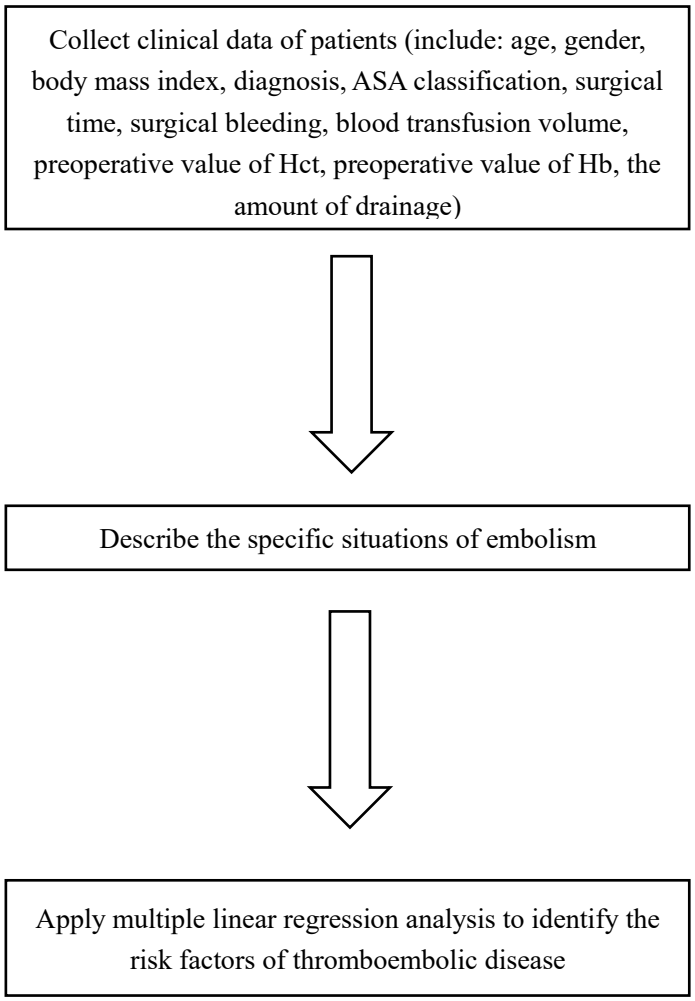
Study objectives The primary objective of this part is to describe the situations of thromboembolic disease in gynecological surgery like the different symptoms and locations of embolism. The secondary objective of this study is to identify the risk factors of thromboembolic disease using multiple linear regression analysis.

Trial design This is an retrospective cross-sectional observatory trial. After signing of informed consent, the electronic medical data of patients undergoing gynecological surgery but developing embolism unfortunately will be analyzed retrospectively in this study. The symptoms of embolism like dyspnea, chest pain, hemoptysis and syncope during the procedure is spoken by patines and recorded by her doctor in charge. They are also responsible for writing down the location of embolism. All patients have complete blood counts before the operation and on the second or the third post-operative day. The risk factors of it can be identified using the multiple linear regression analysis. An overview of the study design is shown in Figure 1.



Sample size The planned sample size was based on data from a previous study, in which the standard deviation was 5. We assumed an one-tailed α error of 0.05 and a sampling error of 1.0. we propose to enroll 60 participants and allow for a dropout rate of 10% for an effective sample size of 54.

Inclusion criteria

1. Volunteer to participate in the study with informed consent;
2. Females aged 20-80 who are confirmed with some gynecological diseases and are treated with surgery but embolism happens unfortunately.

Exclusion criteria

1. Pregnancy, lactation, postmenopause, or planned pregnancy within two years;
2. Patients with blood diseases prone to thrombosis and those with a history of thrombus were excluded;
3. History of hyperparathyroidism, infectious diseases (tuberculosis, AIDS), autoimmune diseases, or digestive system diseases (malabsorption, crohn disease and dysentery);
4. Other diseases or heavy injuries that will interfere with the results;
5. Simultaneous participation in another clinical study with investigational medicinal product(s) or researcher thinks the subjects are not suitable for this trial.

Outcomes measures

The primary outcome is the percentage of different symptoms of thromboembolic disease(%) The secondary outcomes are the location of embolism according to the results of multiple linear regression analysis.

Withdrawal Subjects must be withdrawn from the study when one of the following criteria occurs:

1. At their own request. At any time during the study and without giving reasons, a subject may decline to participate further. The subject will not suffer any disadvantages as a result;
2. In the investigator's opinion, continuation of the study treatment would be harmful to the subject's health;
3. Obvious non-compliance;
4. Lost to follow-up;
5. Pregnancy;

Safety assessments Safety will be assessed by renal and liver function test, electrolyte, routine blood test. Other indicators are detected during the operation and rehabilitation period. The occurrence of any adverse events in participants will be recorded in the case report forms during each patient visit. We will withdraw patients who have severe adverse events, as it is unsafe for them to continue the trial. Meanwhile, we will give them relevant medical care and follow them up until the reaction has terminated.

Statistical analysis

Multiple linear regression analysis was applied to evaluate the risk factors of embolism related to 14 independent variables including four qualitative variables(hypertension, diabetes mellitus, diagnosis according to the FIGO staging system and the pathological tumor type) and eight quantitative variables (age, BMI, the numbr of lymph nodes, the interval between biopsy and operation, surgical time, surgical bleeding, postoperative anticoagulant time, preoperative value of Hb, preoperative value of RBC and preoperative value of Hct). All statistical analyses were performed by SPSS 17.0 software package and the level of statistical significance was set at $P<0.05$. All independent variables were incorporated into the model using the method of “Enter”. Data are

presented as mean ± standard deviation.