Study Title

Point-of-care Management of Coagulopathy in Lung Transplantation

Clinical trial number

NCT03598907

Date

01/01/2018

Methodology:

Patients undergoing bilateral lung transplantation (120 patients) will be randomized into 2 groups using computerized generator of random numbers. The study protocol will be registered in the Clinical Research Database and a clinical trial number (CTN) will be obtained and written informed consent will be obtained from patients before lung transplantation.

The first group of existing „standard care" - the approach to bleeding patient will be based on clinical experience of the anaesthetist, practically meaning administering crystalloids, colloids (hydroxyethyl starch or gelatin), fresh frozen plasma and erythrocytes to restore normovolemia and platelets, fibrinogen, prothrombin complex concentrate, von Willebrand factor, tranexamic acid, all products giving „blindly" when it comes to diagnosis and treatment of coagulopathy.

The second group of „point-of-care" approach to the diagnosis and treatment of perioperative bleeding and coagulopathy will be conducted on the basis of the results of the POC methods ROTEM, PFA 200 and Multiplate (prothrombin complex concentrate, fibrinogen, platelets, von Willebrand factor, tranexamic acid). A solution of 5% albumin and erythrocytes (to keep haemoglobin level over 100 g/l as it is critical for normal primary haemostasis) will be used to keep normal circulating volume and to compensate for perioperative blood loss.

Blood samples will obtained and analysed by ROTEM, PFA 200 and Multiplate, as well as the level and function of von Willebrand factor (multimers assay, ristocetin cofactor and collagen binding assay) will be performed in all patients:

1. before lung transplantation, upon patient arrival to hospital before surgery (as a control)
2. after lung transplantation, during admission of patient to postoperative intensive care unit
3. in the „POC" group also in the operating room (ROTEM, Multiplate and PFA 200) during surgery

The PGD score will be evaluated post-operatively and in the following way: severity of PGD is defined in four degrees and is evaluated using partial arterial oxygen pressure (PaO2) and inspired fraction of oxygen ratio (FiO2) ratio and simultaneously evaluating X-ray finding of the lungs as soon as possible after reperfusion (time 0) and after 48 and 72 hours after lung reperfusion.

- Grade 0 - PaO2/FiO2 ratio of any value but no pulmonary edema on chest X-ray
- Grade 1 - PaO2/FiO2 > 300 and presence of pulmonary edema on chest X-ray
- Grade 2 - PaO2/FiO2 200 - 300 and and presence of pulmonary edema on chest X-ray
- Grade 3 - PaO2/FiO2 < 200 and presence of pulmonary edema on chest X-ray or patients in need of postoperative ECMO support or nitric oxide therapy

To exclude the possible thrombotic complication of any of these approaches, each patient will be screened ultrasonographically for venous thrombosis 72 hours postoperatively (vena poplitea, vena femoralis, vena jugularis, and vena subclavia bilat) and thrombotic complications will compared between groups.

Also other parameters will be compared between groups:

- clot strength and whole coagulation profile before and after surgery using ROTEM, PFA 200 and Multiplate and evaluation of the functional level of von Willebrand factor. Correlation of coagulation profile with blood loss in the operating room and postoperative blood loss will be also assessed.
- amount of perioperative blood loss in the operating room at the end of surgery and 24 hours after surgery (blood loss will measured as amount of blood in the suction container in operating room and as amount of blood in the chest drain in ICU postoperatively)

- number of transfusion products administered in operating room and in postoperative ICU
- duration of invasive and noninvasive mechanical ventilation and time to extubation (hours), duration of stay in the postoperative ICU and overall in hospital before discharge home (days)
- morbidity of patients (SOFA score at 24, 48 and 72 hours after lung transplantation), morbidity and mortality among patients in 30, 90 and 365 days
- incidence of lung graft rejection during whole period of hospitalisation

Time schedule: 4 years During the 3-years period recruitment of patients will be done and in the 4-th year data will be analysed and published in valuable journals.

Investigators expect a lower consumption of blood transfusion products and infusion solutions in the POC group.

In case of lower PGD incidence in the POC group investigators expect shorter time of mechanical ventilation, a shorter period of hospitalization at the postoperative ICU and in the hospital overall and a lower incidence of pulmonary graft rejection.

Investigators expect lower morbidity and mortality of patients in the POC group.

Investigators also believe that the POC approach will reduce the total hospitalisation costs.

Statistics

There is no statistical plan such as „power analysis", as this is a pilot study.