SSC Subcommittee Project/Collaborative Project

NAME OF PROJECT:

Validation of global fibrinolytic assays to be used to identify uncontrollable bleeding due to hyper fibrinolysis

Subcommittee

Fibrinolysis

Person responsible (Chair / Principal Investigator): Tetsumei Urano

Description Abstract

State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Suggested length is 2-3 paragraphs.

There is a growing demand for a quick and reliable assay method to assess residual fibrinolytic resistance to promptly treat bleeding patients caused by hyperfibrinolysis state. Due to the facts that the natural substrate of fibrinolysis is fibrin and that the presence of fibrin largely modifies fibrinolytic activity clot lysis assays seem suitable to detect a state of hyper fibrinolysis. In this project we'll verify several new candidate assay methods established after our previous evaluation (Ref. 1) and publish a consensus guidance of hyperfibrinolysis assessment.

Design and methodology (Data expected to collect, sample size and statistical analysis):

Describe concisely the research design and methods for achieving these goals. Suggested length 2-3 paragraphs

In the SSC symposia in 2024 and 2025, we invite several laboratories having new assays for hyper fibrinolysis. We then recruit other laboratories (minimum 3) which carry out several candidate assays using plasma samples having hyper fibrinolysis which are obtained from several clinical departments (approximately 20 samples). After verifying these assay methods referring the patients clinical data, both the advantages and disadvantages of these assay methods would be clarified. Based on these results, we'll write a consensus guidance of hyperfibrinolysis assessment.

Study population (Inclusion, exclusion, eligibility) (patient population; recruitment of participating institutions/physicians and subjects; minimum number needed; expected number):

Suggested length 2-3 paragraphs

Laboratories which carry out will be recruited in addition to Hamamatsu Medical University (Yuko Suzuki and Tetsu Urano) and University of Nebraska Medical Center (Chris Barrett). Plasma samples (control: 10, moderate bleeding with better outcome: 10, severe bleeding with

poor outcome: 10) will be collected from several clinical laboratories including Hamamatsu Medical University and University of Nebraska Medical Center.

Expected timeline:

Project stage/set up: 2024 June
Launch: 2024 June
Duration: three years
Finalization/analysis: 2026
Reporting: 2027

Expected outcomes (ie. publications):

Publication type (SSC Communication, Guidance document or original article):

Guidance

Description of project set/up and management, needed infrastructure and resources (summary):

Laboratory group which carries out assays.

Collection of plasma samples and their distribution to the laboratories.

Possible references:

1. Ze Zheng, Liliya Mukhametova, Michael B Boffa, Ernest E Moore, Alisa S Wolberg, Tetsumei Urano, Paul Y Kim. Assays to quantify fibrinolysis: strengths and limitations. Communication from the International Society on Thrombosis and Haemostasis Scientific and Standardization Committee on fibrinolysis. Journal of thrombosis and haemostasis : JTH 21(4) 1043-1054 2023