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Standardization of bleeding assessment in immune thrombocytopenia: report from the International Working Group

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Abstract

In a previous publication on new terminology, definitions, and outcome criteria for immune thrombocytopenia (ITP), the International Working Group (IWG) on ITP acknowledged that response to treatment should consist of clinically meaningful end points such as bleeding manifestations and that platelet count may not be the ideal parameter for capturing the benefits of therapy. The IWG now proposes a consensus-based ITP-specific bleeding assessment tool (ITP-BAT) with definitions and terminology consistent with those adopted for other bleeding disorders. Bleeding manifestations were grouped into three major domains: skin (S), visible mucosae (M), and organs (O), with gradation of severity (SMOG). Each bleeding manifestation is assessed at the time of examination. Severity is graded from 0 to 3 or 4, with grade 5 for any fatal bleeding. Bleeding reported by the patient without medical documentation is graded 1. Within each domain, the same grade is assigned to bleeding manifestations of similar clinical impact. The "worst bleeding manifestation since the last visit" (observation period) is graded (a suitable database collection form is provided), and the highest grade within each domain is recorded. The SMOG system provides a consistent description of the bleeding phenotype in ITP, and the IWG unanimously supports its adoption and validation in future clinical studies.

Conclusions: The proposed method for the production of PL by sonication could be a safe, efficient and fast substitute of FBS, without the potential risks of FBS.