



## No. 33 – Assessment of Bleeding Severity

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Title: **Assessment of Bleeding Severity in ITP**

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When first diagnosed, patients with immune thrombocytopenic purpura (ITP) might have their platelet counts monitored as often as once a week; however, with time the office visits become less frequent. Between visits both the physician and the patient are unaware of the platelet count but instead rely on the bleeding symptoms to inform them of the disease status. This is okay however because bleeding is often times a more accurate determinant of how a patient is doing from day to day than the platelet count. Being able to describe bleeding manifestations is therefore an important component to understanding how patients are doing. A systematic way of assessing bleeding severity in patients with ITP gives us several valuable tools as physicians. First, it allows us to communicate with patients about the severity of their disease during times when they are not closely followed in our clinic and when we do not know their platelet count. Second, individual treatment decisions can be made based on clinical rather than laboratory data. Finally, relying on bleeding signs and symptoms rather than the platelet count gives researchers a powerful tool for assessing the effects of medications in clinical trials.

Two bleeding severity measures specific to ITP have been published and applied in clinical investigations. In 1997, Paula Bolton-Maggs and Isabel Moon in the U.K. created a measure to assess bleeding based on the degree of bruising, petechiae, nosebleeds and heavy menstrual periods, etc and if it was considered to interfere with the patient's daily living. The measure categorized patients as being asymptomatic or as having mild, moderate or severe bleeding. Severe bleeding was defined as episodes requiring hospital admission and/or blood transfusions or symptoms interfering seriously with quality of life. Another measure developed in 2002 by George Buchanan and Leah Adix in Dallas also assessed overall bleeding using a severity scale of 0 (no bleeding) to 5 (severe hemorrhage), it more specifically included individual scores for skin findings, oral bleeding, and nosebleeds. While these measures begin to allow physicians to better classify bleeding symptoms they also bring up several points that merit discussion.

Many factors may determine the severity of the bleeding. These include the site and duration of bleeding, if the bleeding is recurrent or happens just once, and if it interferes with a patient's daily activity. For example, looking specifically at nosebleeds, it becomes important to establish what is considered more severe: one nosebleed which lasts for 45 minutes or 10 nosebleeds, each of which only lasts for 10 minutes, but causes the patient to have to leave work for the day. It may be that these are considered to be similarly severe by the patient and physician, but for different reasons. When looking at specific examples such as this, one can see how defining bleeding severity might become difficult. In order to help us answer these questions we can first evaluate objective measures, (e.g., the hemoglobin or red blood cell count). A sharp decline in hemoglobin, leading to anemia, provides evidence that a patient has experienced substantial blood loss. This objective marker is therefore often included in the bleeding severity measures and is a useful indicator of bleeding severity. Another factor, which may seem objective on the surface and often included in measures of severity, is medical interventions. It is implied that patients who require an intervention such as blood transfusion, steroids, IVIG or, in the case of nosebleeds, nasal packing have more severe bleeding. However, the use of these treatments is not as objective as they may appear. The decision to treat or not to treat might depend more on the physician making the decision and their personal preference and thresholds, rather than the actual degree of bleeding or what the patient might desire. It is usually best to avoid the use of medical interventions to classify bleeding severity as they may "speak" more to the treating physician than the patient. It is also important to distinguish bleeding severity from health-related quality of life (HRQOL), a topic given much

attention in recent issues of *The Platelet*. Bleeding symptoms can result in time lost from work or anxiousness and distress over the appearance of bruises. While these are important indicators of quality of life, they do not necessarily reflect the severity of bleeding. Each patient might have a different perspective on their disease, acceptance of their symptoms, or other contributing life factors that influence how a specific bleeding problem affects their emotional and physical well-being. Therefore, a bleeding severity measure should focus only the symptom itself, while HRQOL should address the broader impact of that symptom on each individual.

Other challenging questions exist when considering the application of these bleeding severity measures. If the scoring or measurement method is truly going to be a marker of overall disease severity then it must account for symptoms experienced by patient in between their visits to the physician. It might be best to have patients keep a daily log of their symptoms so that we will not be missing smaller, yet potentially important episodes of bleeding. Lastly, it needs to be brief enough to be completed during a busy clinic visit yet inclusive enough to obtain information even on patients with little bleeding.

The design and analysis of a bleeding severity measure, which meets all of the above criteria, is the primary focus of my ongoing research efforts. Having such a measurement tool will improve communication between patients and physicians. It will also allow researchers to look beyond the platelet count when assessing patient outcomes in clinical research. Finally, such a tool, when used along side platelet count and HRQOL measures, will give us more insights into the relationship between these measures and permit us to evaluate the full impact of the disease on patients. Ultimately, this will lead to better treatment of our patients.