The Preoperative Bleeding Time Test Lacks Clinical Benefit

College of American Pathologists’ and American Society of Clinical Pathologists’ Position Article

Powers Peterson, MD; Timothy E. Hayes, MD, DVM; Charles F. Arkin, MD; Edwin G. Bovill, MD; Robert B. Fairweather, MD; William A. Rock, Jr, MD; Douglas A. Triplett, MD; John T. Brandt, MD

The major conclusions of this position article are as follows: (1) In the absence of a history of a bleeding disorder, the bleeding time is not a useful predictor of the risk of hemorrhage associated with surgical procedures. (2) A normal bleeding time does not exclude the possibility of excessive hemorrhage associated with invasive procedures. (3) The bleeding time cannot be used to reliably identify patients who may have recently ingested aspirin or nonsteroidal anti-inflammatory agents or those who have a platelet defect attributable to these drugs. The best preoperative screen to predict bleeding continues to be a carefully conducted clinical history that includes family and previous dental, obstetric, surgical, traumatic injury, transfusion, and drug histories. A history suggesting a possible bleeding disorder may require further evaluation; such an evaluation may include performance of the bleeding time test, as well as a determination of the platelet count, the prothrombin time, and the activated partial thromboplastin time. In the absence of a history of excessive bleeding, the bleeding time fails as a screening test and is, therefore, not indicated as a routine preoperative test.

Background Information

Historically, the bleeding time test has been used to evaluate the integrity of primary hemostasis. The undocumented, but widespread, assumption is that the bleeding time correlates better with a hemorrhagic tendency in disorders of platelet function than any other in vitro test. As a consequence, the bleeding time is often determined prior to invasive procedures in an attempt to predict the risk of hemorrhagic complications. Recently, the indications for the clinical use of the bleeding time have come under closer scrutiny, resulting in an increase in the controversy regarding the appropriate use of the bleeding time test. Some of the underlying issues in this controversy include a desire to have a test that accurately predicts the risk of procedure-associated hemorrhage, fear of litigation in the event of a major hemorrhage, lack of understanding of the limitations of the bleeding time test, efforts to control rising health care costs, and increasingly limited laboratory resources. The goal of this position article is to generate a consensus that a routine preoperative bleeding time test is not warranted in the patient who does not have a history of a bleeding disorder.

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sphygmomanometer to elevate capillary pressure and maintain a constant capillary tone, thereby controlling a major variable—collapse of the vessel wall. Almost 25 years ago, Mielke et al introduced the template technique to address standardization of the length and the depth of the incision. More recently, disposable devices based on the approach by Mielke et al have been introduced. Recent work suggests that these modifications to the Ivy technique have not notably improved the reproducibility, sensitivity, or specificity of this procedure. Despite these attempts to standardize technique, the bleeding time test continues to be affected by numerous technical variables and clinical conditions (Table).

There is a relationship between the platelet count and the bleeding time that was shown in the classic study of Harker and Slichter. Their study of clinically stable, nonmedicated subjects with pure platelet production defects showed that the bleeding time is normal when the platelet count is greater than 100 × 10^9/L. However, the results of their study cannot be generalized because the patient population they examined is not representative of the patients for whom the bleeding time might be used to make clinical decisions. There are clinical conditions, such as systemic lupus erythematosus and uremia, for which the bleeding time may be prolonged with mild thrombocytopenia and for which bleeding problems are more likely a reflection of dysfunctional platelets rather than mild thrombocytopenia. Furthermore, there are conditions, such as idiopathic thrombocytopenic purpura, for which the bleeding time may be shorter than would be expected based on the platelet count. Because the correlation between the bleeding time and the platelet count may vary markedly, the bleeding time should not be used as an estimate of the platelet count.

STUDIES CONCERNING THE PREOPERATIVE USE OF THE BLEEDING TIME TEST

One to 2 million bleeding time procedures are performed each year in the United States, making it one of the most widely used tests of hemostasis. Most of these bleeding time tests are probably performed in anticipation of surgery or other invasive procedures. The bleeding time test was introduced in an era when clinical tests were not scrutinized for their predictive value, quickly became established as a “routine” test, and has been promoted as an aid to diagnosis, prognosis, and the monitoring of therapy. It was assumed to be an effective screening test for congenital disorders of platelet function and a predictor of the risk of bleeding. Despite its widespread clinical use, the bleeding time test is not a good preoperative screening tool for the general population.

Preoperative Evaluation of Risk of Bleeding

Excessive perioperative bleeding secondary to a preexisting hemorrhagic disorder in a patient with no history of excessive bleeding is a rare event. When a test is used to screen a low-risk population for an uncommon event, a positive result is often a false positive. In other words, the predictive value of a positive test in such a situation is poor. Barber et al reviewed 1941 consecutive template bleeding times, approximately 95% of which were used for a preoperative screen. Only 110 (6%) of the patients were found to have an abnormal bleeding time. Eighty-three (75%) of these patients could have been predicted to have an abnormal bleeding time from an adequate clinical history. No obvious cause for the prolonged bleeding time could be found in the other 27 patients. Seventeen of these 27 patients later underwent a second bleeding time test; of these tests, the results for 12 were normal, suggesting that most of these long bleeding times were false positives due to technical artifact.

There are insufficient data to accurately calculate the sensitivity, specificity, or predictive value of the bleeding time regarding perioperative or postoperative hemorrhage. Rodgers and Levin were able to identify only 2 published studies with sufficient data to prepare receiver operating characteristic curves. The receiver operating characteristic curves from these studies indicated that the bleeding time behaved like a noninformative test in predicting the risk of bleeding.

Recent reviews have highlighted the inability of the bleeding time to predict excessive surgical bleeding. Multiple studies have found no relationship between the preoperative bleeding time and the amount of blood loss.

Factors Affecting the Bleeding Time Test

*From references 5 and 12 through 18.
†From references 23 through 26, 29 through 36, 38 through 40, and 62.
‡From Rao.19
§From references 18, 22 through 28, and 41 through 45.

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<td>Previous test within 4 h</td>
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<td>Cold applied to adjacent skin</td>
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associated with cardiopulmonary surgery.29,49,54 In one double-blind study, the hemostatic integrity of 101 consecutive patients was evaluated preoperatively by 2 hematologists.39 They stratified the patients into 3 groups according to the anticipated risk of bleeding; 7 of 8 high-risk patients were classified as such based on a prolonged bleeding time. Only 2 of the 17 patients who experienced excessive bleeding were prospectively classified as high risk. Two patients died as a result of excessive intraoperative hemorrhage; neither had been classified as high risk. Ferraris and Swanson56 prospectively evaluated the conditions of 129 patients requiring urgent, unplanned, general surgical procedures. Eight of these patients had a prolonged bleeding time preoperatively; none of these 8 patients had excessive bleeding. Handler et al57 observed 38 patients with postoperative bleeding in a series of 1445 patients undergoing tonsillectomy; there was no difference in the mean bleeding time between patients with (5.46-minutes) and without (5.34-minutes) postoperative bleeding. In a subsequent study, they identified 3 of 1603 patients with a long bleeding time prior to tonsillectomy. The results of a subsequent bleeding time test were abnormal in only one of these patients; this patient had von Willebrand disease and also had a prolonged activated partial thromboplastin time.30

There is little information regarding the efficacy of the bleeding time test in predicting hemorrhagic risk associated with specialized surgery or other invasive procedures. In a prospective study of 139 patients undergoing cataract extraction, hyphema developed in 3 (19%) of 16 patients with a prolonged bleeding time compared with 10 (9.5%) of 105 patients with a normal preoperative bleeding time.38 Although these data suggest a trend toward an increased risk of hyphema with a long bleeding time, the difference was not statistically significant. Furthermore, the relationship between aspirin ingestion and prolongation of the bleeding time was not addressed. Amrein et al59 addressed the effect of perioperative administration of aspirin on bleeding in patients undergoing hip surgery. While there was a slight increase in blood loss associated with the administration of aspirin, there was no association between the preoperative bleeding time and surgical blood loss.

Hematoma formation is a rare, but feared, complication of epidural and spinal anesthesia.60-64 The potential association between the common use of nonsteroidal anti-inflammatory drugs, abnormalities of platelet function, and hematoma formation have led some to recommend that a bleeding time test be performed before epidural anesthesia and that a bleeding time in excess of 10 minutes is a relative contraindication for epidural anesthesia.64 There are inadequate data to support this conclusion.38 Horlocker et al65 found that 39% of the patients undergoing spinal or epidural anesthesia were exposed to antiplatelet medications in the preoperative period. Neurologic complications in association with the procedure did not develop in any of these patients. Odom and Sih66 reported their experience with 1000 cases of epidural anesthesia given to patients receiving oral anticoagulants. They observed no complications that could be related to bleeding or hematoma formation in the extradural space. There are anecdotal cases of spinal subdural bleeding in association with the use of antiplatelet medications; however, the preoperative bleeding time has not been uniformly prolonged in these cases.31,32 Finally, as discussed in the section on “Evaluation of Risk of Bleeding in Patients Taking Aspirin or Nonsteroidal Anti-inflammatory Drugs,” the bleeding time is not a sensitive test when used to detect the preoperative use of aspirin. Thus, even if there is a slight association between the preoperative use of aspirin and hematoma formation following epidural or spinal anesthesia, the bleeding time is not an adequate test to identify patients who have taken aspirin.

Evaluation of Risk of Bleeding in Patients Taking Aspirin or Nonsteroidal Anti-inflammatory Drugs

The bleeding time is also often misused to identify patients who may have recently ingested a drug, usually aspirin, known to interfere with platelet function. A history of aspirin ingestion has been associated with increased blood loss in some clinical settings, including open heart surgery, hip surgery, delivery of a neonate, and gastrointestinal bleeding.35-38 The clinical desire to identify such patients is easy to understand. However, there are 2 basic problems with using the bleeding time for this purpose: (1) the bleeding time is not effective in identifying such patients and (2) the correlation between bleeding and prolongation of the bleeding time is poor in such patients.

The ingestion of 650 mg of aspirin by volunteers resulted in a method-dependent mild increase in the bleeding time compared with the individual’s baseline bleeding time.7,26 However, in most of the individuals studied, the bleeding time remained within the normal range. In a study of patients receiving long-term aspirin therapy, the mean (±SD) bleeding time in patients receiving 300 mg of aspirin a day was 217± 69 seconds; in patients receiving 1200 mg of aspirin a day, it was 240± 60 seconds; and in patients receiving placebo, it was 217± 63 seconds.37 In a case-control study, Bashein et al67 found that the preoperative bleeding time (±SD) in patients taking aspirin within 7 days of open heart surgery was 5.5± 2.2 minutes compared with 4.9± 1.1 minutes in those not taking aspirin during this period. Although the difference in mean bleeding time was significant, there was too much overlap between the 2 groups to make the bleeding time a clinically useful procedure. In a study of patients requiring unexpected surgery, Ferraris and Swanson56 found that the bleeding time was prolonged in only 8 of 22 patients with a history of recent aspirin ingestion, documented by suppression of thromboxane B2 levels. These studies indicate that the bleeding time cannot be used to reliably identify patients who have recently received aspirin.

Although a history of aspirin ingestion has been associated with bleeding in patients with some conditions, there is little evidence that increased blood loss in such patients can be predicted by the bleeding time. In their evaluation of the effect of aspirin ingestion on bleeding associated with hip surgery, Amrein et al59 found no correlation between increased bleeding and a bleeding
time of greater than 10 minutes or an aspirin-induced prolongation of 4 minutes over baseline. As noted previously, Ferraris and Swanson found no relationship between surgical bleeding and either preoperative bleeding time or history of aspirin ingestion in their study of patients requiring urgent surgical procedures. The relationship between a history of aspirin ingestion, preoperative bleeding time, and perioperative blood loss has also been examined in patients undergoing cardiopulmonary bypass surgery. These studies have shown that there is an association between a history of aspirin ingestion and blood loss but that there is no relationship between the preoperative bleeding time and blood loss. Finally, O’Laughlin et al found that while the skin bleeding time was prolonged after aspirin ingestion, the gastric bleeding time following a gastric biopsy was normal, suggesting that a long skin bleeding time may not accurately predict the response to vascular injury at other sites.

Therefore, the most effective method of identifying patients who may be at risk because of aspirin ingestion is the clinical history. The critical period for exposure to aspirin seems to be approximately 3 days prior to an invasive procedure. A recent study documented that platelet function, as measured by thromboxane A2 production and aggregation studies, returned to normal 4 days after the cessation of aspirin therapy. Another study showed that aspirin-induced prolongation of the bleeding time lasts no longer than 48 hours. The prolonged bleeding time in patients taking aspirin may be shortened after the administration of desmopressin acetate; however, there is no evidence that this translates into decreased perioperative blood loss.

**Evaluation of Risk of Bleeding in Patients With Uremia**

Uremia is a complex metabolic disorder that has deleterious effects on hemostasis. The hemostatic defect associated with uremia is complex and multifactorial and has not yet been fully delineated. In recent years, it has become evident that a low hematocrit is associated with a prolonged bleeding time in patients with uremia and that correction of the hematocrit by transfusion or use of recombinant erythropoietin is associated with normalization of the bleeding time in most patients. Uncontrolled studies have suggested that the normalization of the bleeding time with increasing hematocrit is associated with a decreased incidence of bleeding. This effect seems to be due to improved interaction between circulating platelets and the vessel wall, as well as alteration of a plasma defect associated with uremia.

The bleeding time has also been used to assess other forms of intervention in patients with uremia. Several studies have shown that the bleeding time decreases following the intravenous or subcutaneous administration of desmopressin acetate within 4 to 6 hours. The bleeding time has also been used to monitor the response to cryoprecipitate or conjugated estrogens. In all these reports, there is anecdotal evidence that correction of the bleeding time was associated with decreased clinical bleeding. Indeed, it has been suggested that the bleeding time may be the best indicator of bleeding risk in patients with uremia. Other studies evaluating the relationship between bleeding of widely varying severity and prolongation of the bleeding time have failed to establish the use of the bleeding time for the prediction of clinically severe bleeding in advance of its occurrence. In particular, the study by Eknoyan et al showed that a decline in prothrombin consumption was more predictive of bleeding than any other parameter studied, including the bleeding time. Although some studies have shown a reasonable correlation between the bleeding time and “clinical” bleeding (as distinguished from “surgical” bleeding) in patients with uremia, no controlled study has shown that patients with prolonged bleeding times have more clinically significant complications than those with normal bleeding times. Thus, the bleeding time may be useful for monitoring the response to therapy in patients with uremia. However, there is little direct evidence indicating that the bleeding time can be used to predict the risk of bleeding in these patients, particularly in a patient undergoing an invasive procedure.

**CONCLUSIONS**

In addressing the issues of concern regarding this laboratory test, we conclude the following:

1. In the absence of a clinical history of a bleeding disorder, the bleeding time is not a useful predictor of the risk of hemorrhage associated with surgical procedures.
2. A normal bleeding time does not exclude the possibility of excessive hemorrhage associated with invasive procedures.
3. The bleeding time cannot be used to reliably identify patients who may have recently ingested aspirin or nonsteroidal anti-inflammatory agents, or who have a platelet defect attributable to these drugs.

The best preoperative screen to predict bleeding continues to be a carefully conducted clinical history, which includes family and previous dental, obstetric, surgical, traumatic injury, transfusion, and drug histories. A patient with a history suggesting a possible bleeding disorder may require further examination. In the absence of a history of excessive bleeding, the bleeding time fails as a screening test and is, therefore, not indicated as a routine preoperative test.

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From the Departments of Pathology, Cornell University Medical College, New York, NY (Dr Peterson); Maine Medical Center, Portland (Dr Hayes); University of Vermont College of Medicine, Burlington (Dr Bovill); Dartmouth-Hitchcock Medical Center, Lebanon, NH (Dr Fairweather); University of Mississippi Medical Center, Jackson (Dr Rock); Ball Memorial Hospital, Muncie, Ind (Dr Tripplett); and Ohio State University College of Medicine, Columbus (Dr Brandt); and the Department of Laboratory Medicine, Boston University Medical Center, Boston, Mass (Dr Arkin). Dr Peterson is now with the Department of Laboratory Medicine, Boston University Medical Center, Boston, Mass (Dr Arkin).
REFERENCES
