BLEEDING TIME: IS IT A USEFUL CLINICAL TOOL?

S. W. O'KELLY, E. G. LAWES AND J. B. LUNTLEY

SUMMARY

The bleeding times of five volunteers were assessed individually by each of 12 observers. The reliability of the measurements obtained was examined by comparing statistically the variability between subjects and between observers. This variability was found to be similar for both groups. Consequently, we suggest that the bleeding time estimation is an unreliable test and should not be used in isolation without reference to the salient features of a history and examination, when determining if an individual patient is at risk of haematoma formation as a complication of regional anaesthetic techniques.

KEY WORDS


The incidence of serious non-fatal complications associated with regional anaesthesia is extremely low. Amongst these complications is the development of extradural haematoma after puncture of an extradural blood vessel. This rarely gives rise to a significant neurological deficit [1]. Although the incidence of venous puncture while performing extradural block is estimated at about 18%, formation of significant haematoma is, fortunately, much rarer. In a recent case report, Tekkok and colleagues stated that a search of the world literature revealed only five cases of this complication [2]. Disorders of coagulation are reasonably assumed to predispose to an increased incidence of the complication; to our knowledge, no case of extradural haematoma formation as a result of abnormal platelet function has been reported. Despite this, great consideration is given to situations which require regional techniques in patients in whom abnormalities of platelet number or function may co-exist.

In the absence of frank signs of a coagulation disorder and when regional anaesthesia is indicated, the risk of increased bleeding is currently assessed primarily by laboratory diagnosis, including measurement of platelet numbers. The benefit of this laboratory investigation has been questioned in the light of a poor correlation between platelet count and bleeding time [3]. Recently, it has been suggested that assessment of platelet function by the bleeding time rather than by establishing numbers may be more useful in identifying specifically abnormal haemostasis, thus minimizing the risk of haematoma formation in those patients at risk during regional anaesthetic techniques [4].

Patients considered to be at increased risk of haematoma formation as a result of abnormal platelet activity include obstetric patients suffering from either gestational proteinuric hypertension or who are being treated with aspirin to prevent fetal growth retardation. Quantification of the increase in bleeding tendency in these patients using the bleeding time is superficially attractive because of its apparent ease. In order to determine the usefulness of this technique as a clinical tool, we have assessed observer variability in the estimation of bleeding time. If the bleeding time is to be useful and reliable, the results of this test must be simple and reproducible.

METHODS AND RESULTS

Five members of the staff of the Shackleton Department of Anaesthesia volunteered to be the subjects of the study. Each subject agreed to estimation of bleeding time as described in the procedure of the Simplate II test package. A sphygmomanometer cuff was placed around the upper arm and inflated to a pressure of 40 mm Hg. A standard cut, 1 mm in depth and 5 mm in length was made, using the Simplate device, in the anterior aspect of the forearm at right angles to the long axis of the limb. The cut was dabbed periodically with wood-free absorbent tissue paper. Twelve untrained observers, also members of the anaesthetic department and of all grades of seniority, were instructed, as described in the procedure, to observe each subject and record their estimation of each individual's bleeding time. In this way, 12 estimations were made of the bleeding times of five subjects. This method of observation was felt to reflect more realistically the circumstances in which this test would be applied in clinical practice by anaesthetists, rather than by specialist laboratory technicians. The results of these observations were assessed by observer and by subject.

Statistical analysis of the differences between the means for the mean bleeding time failed to reveal a statistically significant difference between subjects.

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No subject would have been excluded from receiving a regional anaesthetic technique if the mean bleeding time was compared against the standard cut-off point for normal subjects of 10 min. If individual results were assessed, then both subject 1 and subject 2 would have been excluded by at least one observer. There was no statistically significant difference in the mean bleeding times between observers—that is, no observer produced consistently high or low estimates of the bleeding times. The range of results was similar in all subjects (table I).

Further statistical analysis was used to examine the quality of the bleeding time test as a discriminatory tool. A variance component estimation procedure examined the estimated SD between subjects (0.5868) and the estimated SD between observers (0.5053). A good test measurement should have much less variability between observers than the variability between subjects. This would appear to imply that the observer (anaesthetist) was as likely to be the source of an abnormal result as the subject (patient).

**Comment**

An imbalance between prostacyclin and thromboxane A2 has been implicated in the aetiology of gestational proteinuric hypertension. Aspirin, which may reverse this change, may be used in small doses to help to prevent the development of the pathological consequences of this condition. The use of small doses of acetylsalicylic acid may significantly prolong the bleeding time, and testing for bleeding time abnormalities is seen by some authors to be a necessary action before inserting extradural catheters in these patients.

Estimation of the bleeding time is by no means a straightforward procedure. Channing-Rogers and Levin [5] have shown that the pathophysiology of an abnormal bleeding time remains poorly understood. The bleeding time is affected by a large number of diseases, drugs, psychological factors, testing conditions and therapeutic actions, not all related directly to platelets. Not least of the factors influencing accurate interpretation of bleeding times is observer error.

Our results support the view that, despite meticulous attention being paid to detail, the measured bleeding time of an individual is subject to wide observer variation. The wide distribution of estimates of each subject's bleeding time demonstrates the poor reliability of any single measurement. It is unclear if this variation is entirely operational, as the standard method for measuring the bleeding time remains largely subjective.

In our study the "cut-off" between normal and abnormal bleeding times was taken as 10 min. This gave a 1 in 3 chance that one in five normal subjects would be counted as abnormal. This amounts to a false positive rate of nearly 7% or, in an obstetric practice of 2000 extradurals per year, would result in about 140 patients being unnecessarily denied extradural analgesia. The financial implications of estimating the bleeding time are not insignificant. The item cost for each Simplate is in the region of £5. Even if relatively few patients were to have their bleeding time estimated, the cost per annum to an average sized obstetric unit may be several thousands of pounds.

In addition to the difficulty we have demonstrated with making the bleeding time estimation reliable, others have argued that the bleeding time estimation may not be a valid measure of clinically significant bleeding. An abnormally large figure may not reflect a clinically significant bleeding tendency. Channing-Rogers and Levin cast doubt on both the specificity and sensitivity of the bleeding time, which they feel may not be sufficient to make meaningful clinical decisions in individual patients [5]. It may be difficult, therefore, to be confident that a single estimate of a patient's bleeding time is an accurate assessment of true bleeding time or a useful indicator of whether or not the patient is likely to suffer clinically significant bleeding.

Until a simple reliable and valid test exists which enables the clinician to predict abnormal platelet number or function, the decision whether or not to place an extradural catheter must depend on the presence of clinical evidence of abnormal coagulation obtained from the history and examination of the patient. In accordance with the editorial views of the *Lancet* [6], we feel that there is very little evidence to support the use of the bleeding time as a diagnostic test in individual patients before using regional anaesthetic techniques.

### Table 1

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