2020 Health Technology Reassessment Report

Bleeding Time

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Summary

Background and Purpose of Assessment

The bleeding time assesses the interaction between platelets and blood vessel walls and reflects the primary hemostasis process caused by vasoconstriction and platelet adhesion and aggregation during the hemostasis process. The number of blood vessels, platelets, and platelet function affect the bleeding time. There is a limitation that it is impossible to determine which of these is the problem by the bleeding time alone when the bleeding time is prolonged. In addition, it is pointed out that the bleeding time has low reproducibility, the difficulty of standardizing the test, and the lack of clinical benefits such as low diagnostic accuracy to evaluate the bleeding risk compared to using an invasive method. Against this background, laboratory medicine experts judged this test item as an item corresponding to low value or obsolete technology used in the medical field and suggested it as the agenda of the health technology re-assessment. Therefore, as part of the health technology re-assessment project, this assessment was intended to evaluate the medical and scientific evidence for the clinical safety and effectiveness of the bleeding time for the purpose of screening for hemorrhagic disorders and pre-operative bleeding risk assessment.

Committee’s Operation

The subcommittee, which consists of a total of 7 experts from the Department of Laboratory Medicine, Department of Hematology-Oncology, Department of Pediatrics, and Department of Evidence-Based Medicine, evaluated the safety and effectiveness of the bleeding time based on the literature through the operation of the subcommittee four times in three months from August 12, 2020, to October 23, 2020. At the 11th Health Technology Reassessment Committee (2020.11.13.) in 2020, the conclusion of the subcommittee was finally reviewed.

Assessment Methods

A systematic review was conducted on the safety and effectiveness of the bleeding time in patients subject to hemorrhagic disorders screening and pre-operative bleeding risk assessment. All assessment methods, including detailed implementation methods, were finalized after discussion of the “bleeding time subcommittee” (hereinafter referred to as the 'subcommittee').

The systematic review was conducted in 3 overseas and 5 domestic databases based on key questions, and the literature selection process was performed

independently by two reviewers according to predetermined literature inclusion and exclusion criteria. In case of disagreement, the final article was decided through subcommittee discussion. The risk of bias assessment on literature was evaluated using QUADAS-II, and two reviewers independently evaluated the finally selected literature. In case of disagreement, a consensus result was reached through the entire subcommittee discussion. For data analysis, quantitative and qualitative analyses were applied. The re-assessment committee decided the recommendation grade based on the assessment results conducted by the subcommittee.

Assessment Results

In this assessment, 20 original articles reporting the bleeding time were reviewed for screening tests for bleeding disorders or for preoperative bleeding risk assessment in a systematic review conducted to re-assess the safety and effectiveness of the bleeding time.

The bleeding time is a diagnostic test that measures the time until bleeding stops after artificially injuring a subcutaneous blood vessel. Safety concerns have been pointed out as an invasive test that can cause bleeding and scarring due to the test, but there has been no literature reporting related safety indicators.

As a result of quantitatively synthesizing four pieces of literature reporting the diagnostic accuracy of the bleeding time to screen for hemorrhagic disorders, the AUC of bleeding time SROC was 0.50, the combined sensitivity was 0.34 (95% CI 0.24-0.46), and the combined specificity was 0.85 (95% CI 0.69-0.93). Based on this calculation, the combined positive likelihood ratio was 2.26 (95% CI 1.17-4.35), the combined negative likelihood ratio 0.78 (95% CI 0.67-0.89), and the combined diagnosis odds ratio was 2.92 (95% CI 0.69-6.20). The diagnostic accuracy of the bleeding time performed to screen for bleeding disorders was at a very low level compared to the comparative test PFA-100. Studies that reported the correlation between the bleeding time and various comparative tests such as bleeding score, platelet count, aPTT, haemostasis time, filter bleeding time, and vWF assay were reviewed. However, the correlation was not consistent by study, test method, and disease.

In one study that evaluated diagnostic accuracy of the bleeding time for the purpose of pre-operative bleeding risk assessment, the bleeding time sensitivity was very low at 0.11. Also, there was no statistically significant relationship in two studies examining the relationship between pre-operative bleeding time results and intraoperative bleeding volume.

Conclusion and Suggestions

The bleeding time subcommittee made the following conclusions based on the assessment results. The bleeding time was 600,000 cases in domestic clinical fields as of 2019, and health insurance claims have been continuing. The bleeding time is not only limited by the diagnostic test itself, such as low diagnostic accuracy and difficulty in standardization of tests, but also limitations that can cause stress and burden on patients and medical staff due to the test limitation. In the current situation where many alternative tests to evaluate bleeding risk already exist, the subcommittee determined that bleeding time was an invalid test to screen hemorrhagic disorders and to assess preoperative bleeding risk based on the systematic review. The Health Technology Reassessment Committee deliberated on 'Bleeding Time' as follows based on the review results of the subcommittee (November 13, 2020).

The Health Technology Reassessment Committee does not recommend the bleeding time for the screening of hemorrhagic disorders and - assessment of preoperative bleeding risk (recommendation grade II). The reasons for the recommendation are as follows. The bleeding time test for the screening of hemorrhagic disorders and assessment of preoperative bleeding risk was considered invalid because of its lower sensitivity compared to alternative tests and lack of consistency with other tests to evaluate bleeding risk.

Keywords

Hemorrhagic Disorders, Bleeding Time