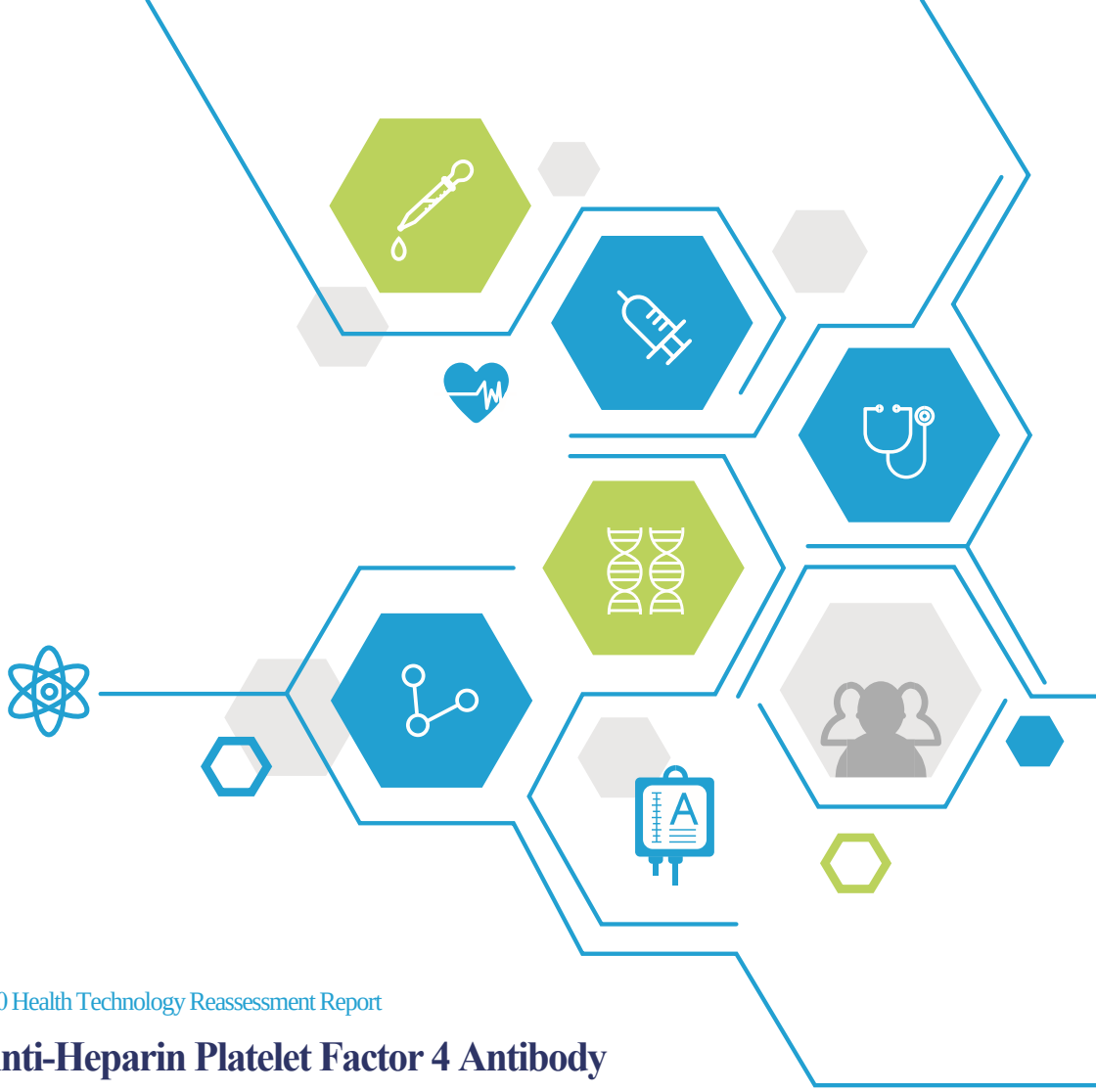

2020 Health Technology Reassessment Report

Anti-Heparin Platelet Factor 4 Antibody [Chemiluminescence Immunoassay]

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Summary

Background of Assessment

The anti-heparin platelet factor 4 antibody [chemiluminescence immunoassay] is a method for diagnosing heparin-induced thrombocytopenia by checking the presence of antibodies to the heparin-PF4 conjugate using a chemiluminescence immunoassay in patients with suspected heparin-induced thrombocytopenia (hereinafter HIT). This technology was evaluated as a new health technology (No. 2013-101) as a result of the 2013 New health Technology Assessment, and 'Anti-heparin/PF4 Antibody [chemiluminescence Immunoassay]' was subsequently registered as a non-benefit item in July (No. 2015-129) according to the decision of the Medical Practice Assessment Committee held in March 2015. The new health technology assessment basis was updated as this technology was selected as a re-assessment agenda at the 3rd Health Technology Reassessment Committee (2020.03.20.) in 2020 as it needed to be reviewed to strengthen coverage.

Afterward, the safety and effectiveness assessment results of the anti-heparin platelet factor 4 antibody [chemiluminescence immunoassay] were finally deliberated at the 10th Health Technology Reassessment Committee (2020.10.16.).

Assessment Method

The safety and effectiveness assessment of anti-heparin platelet factor 4 antibody [chemiluminescence immunoassay] was conducted through a systematic literature review. All assessment methods were determined after deliberation by the “anti-heparin platelet factor 4 antibody [chemiluminescence immunoassay] assessment subcommittee (hereinafter referred to as the ‘subcommittee’)” in consideration of the research purpose. The key questions in the assessment are 1) How effective is the anti-heparin platelet factor 4 antibody test using chemiluminescence immunoassay in the diagnosis of HIT-suspected patients? 2) What is the cost or cost-effectiveness of anti-heparin platelet factor 4 antibody test using chemiluminescence immunoassay? For safety, it was evaluated that this test method does not directly harm the human body because it is an in vitro test that is collected from blood. Effectiveness was evaluated with diagnostic accuracy (sensitivity/specificity, positive/negative predictive value, positive/negative likelihood ratio) and economic-related outcome variables.

A literature search was conducted in 3 overseas databases and 5 domestic databases, and two reviewers independently screened and selected them

according to the literature inclusion and exclusion criteria. Evaluation of the risk of bias in the literature was performed independently by two reviewers using QUADAS-2 and consensus was reached. Data extraction was performed independently by two reviewers using a pre-determined data extraction format, and in case of disagreement, it was agreed upon by discussion with a third party. For data analysis, the results were synthesized using meta-analysis on the pre-defined outcome variables related to diagnostic accuracy. Sensitivity analysis was performed through subgroup analysis according to whether the reference test and 4T score were performed.

Assessment Results

A total of 10 pieces of literature were selected for the assessment of anti-heparin platelet factor 4 antibody [chemiluminescence immunoassay], all of which were foreign documents. Two of the articles included in the study were documents included in the past new health technology assessment reports and were also reflected in this assessment. The level of risk of bias in the literature was analyzed to be low.

Safety

As for the safety of this test, it was evaluated that there was no problem with the safety of the test because it did not directly harm the patient except for the blood sampling process.

Effectiveness

Effectiveness was evaluated based on a total of ten diagnostic method evaluation studies.

As a result of analysis using serotonin secretion test, platelet aggregation test, and flow cytometry as reference standard tests, the sensitivity range of HIT-IgG was reported to be 0.667 to 1.000, the specificity range was 0.734 to 0.970, the sensitivity of HIT-IgGAM was 0.667 to 1.000, and the specificity was reported from 0.730 to 0.970.

The combined sensitivity of the HIT-IgG test was 0.95 (95% CI 0.90, 0.98), the combined specificity was analyzed as 0.94 (95% CI 0.92, 0.96). The combined sensitivity of the HIT-IgGAM test was 0.96 (95% CI 0.90, 0.99), and the combined specificity was analyzed as 0.82 (95% CI 0.80, 0.85), confirming that the test method has high sensitivity and specificity.

In the case of cost-related analysis, the literature evidence was not sufficient, as reported in only two documents. However, it was reported that the use of this test would reduce the cost of testing and alternative anticoagulants by reducing the number of tests per year by 50 cases compared to the heparin-induced platelet activation test (HIPA).

Conclusion and Suggestions

The anti-heparin platelet factor 4 antibody [chemiluminescence immunoassay] subcommittee evaluated the following based on the literature evidence.

The anti-heparin platelet factor 4 antibody [chemiluminescence immunoassay] is a test that can quickly diagnose heparin-induced thrombocytopenia by checking the presence of antibodies to the heparin-PF4 conjugate in patients with suspected heparin-induced thrombocytopenia. It was evaluated as a test method with evidence for safety, effectiveness, and economic feasibility.

Therefore, the Health Technology Reassessment Committee recommended an anti-heparin platelet factor 4 antibody [chemiluminescence immunoassay] test (recommendation grade I-a). (2020.10.16.)

Keywords

Heparin-Induced Thrombocytopenia, Anti-Heparin Platelet Factor 4 Antibody,

Chemiluminescence Immunoassay.