2020 Health Technology Reassessment Report

ADAMTS-13 Activity Assay

[Immune blotting method]

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Summary

Background of Assessment

‘ADAMTS-13 activity assay [Immune blotting method]’ is a technology used to diagnose thrombotic thrombocytopenic purpura and was assessed as a new health technology (HTA-2009-24) in 2009. After being registered in the service/practice list in the Ministry of Health and Welfare Notice No. 2010-53 (July 26, 2010), it was implemented as non-reimbursement. The necessity of generating evidence for safety and effectiveness was confirmed through internal monitoring and expert advice, and it was selected as an agenda item for health technology re-assessment at the 6th Health Technology Reassessment Committee (2020.6.12.-19.) in 2020. After that, the item was deleted and revised as a reimbursement item by adding a ‘Western Blot’ item to the ‘ADAMTS-13 Activity Assay’ column in the service reimbursement list (Ministry of Health and Welfare Notice No. 2020-164). Accordingly, in accordance with the review results of the 8th Health Technology Reassessment Committee (2020.8.14.) in 2020, a re-assessment was performed through a brief literature review. The 10th Health Technology Reassessment Committee (2020.10.16.) in 2020 conducted final deliberation on the safety and effectiveness evaluation results of ADAMTS-13 Activity Assay [Immune blotting method].

Assessment Method and Results

The safety and effectiveness evaluation of ADAMTS-13 Activity Assay [Immune blotting method] was conducted by collecting the opinions of the subcommittee and reviewing guidelines and brief literature.

For safety, the test is performed outside the patient's body by collecting the patient's blood through the subcommittee's discussion, and it was evaluated that there is no safety problem due to the conduct of the test because the sample collection does not directly harm the patient. As a technology that plays a major role in differential diagnosis, it was evaluated that there is no safety problem due to the test results in terms of the stability of the test results.

In terms of effectiveness, there is no other test that can differentially diagnose thrombotic thrombocytopenic purpura and hemolytic uremic syndrome other than clinical symptoms. Therefore, ADAMTS-13 activity assay [Immune blotting method] was evaluated as effective as a test to confirm thrombotic thrombocytopenic purpura and differentiate it from similar diseases. Effectiveness as a test for monitoring and predicting disease recurrence after treatment was reviewed through two pieces of literature. According to the results of ADAMTS-13

activity assay in one literature on patients with hemolytic uremic syndrome, there were significant differences in response rate (OR, 6.77; 95% CI, 1.61-28.54; p=0.005), remission rate (OR, 6.00; 95% CI, 1.69-21.26; p=0.004), exacerbation rate (OR, 0.24; 95% CI, 0.06-0.92; p=0.31), and disease-related mortality (OR, 0.16; 95% CI, 0.03-0.81; p=0.017), indicating that it is a useful test for monitoring and predicting prognosis after treatment. However, there was no significant correlation between ADAMTS-13 activity and treatment outcome in the one literature for patients with thrombotic thrombocytopenic purpura.

Conclusion

The ADAMTS-13 activity assay [Immune blotting method] subcommittee suggested the following.

ADAMTS-13 activity assay [Immune blotting method] is an in vitro test that does not directly harm the patient and the results are also stable. So, it was judged as a technique with no problem in the safety. In addition, in guidelines and previous studies, it is used as a standard test for the confirmation and differential diagnosis of target diseases, and recent literature confirms evidence that it is a useful test for treatment response and outcome prediction. Therefore, it was judged to be an effective technique as a test for diagnosis and differential diagnosis of thrombotic thrombocytopenic purpura from similar diseases, monitoring after treatment, and prediction of disease recurrence.

Accordingly, the Health Technology Reassessment Committee deliberated as follows on ‘ADAMTS-13 activity assay [Immune blotting method]’ based on the review results of the subcommittee (2020.10.16.). ADAMTS-13 activity assay [Immune blotting method] is recommended as a test for definite diagnosis of thrombotic thrombocytopenic purpura and differential diagnosis from similar diseases, monitoring after treatment, and predicting disease recurrence (Recommendation Grade I-a).