2020 Health Technology Reassessment Report

Colloidal Reaction TTT
[Chemical Reaction-Equipment Measurement]
(Thymol Turbidity Test, TTT)

NECA
한국보건의료연구원

Summary

Background of Assessment

Colloidal reaction TTT [Chemical Reaction-Equipment Measurement] is a technology to evaluate liver function through quantitative and qualitative abnormalities of plasma protein components in patients with (suspected) liver disease. This technology corresponds to an obsolete technology in which the number of patients, total usage, and total amount of treatment have been reducing by years, so diagnostic laboratory medicine experts suggested a re-assessment. It was selected as an agenda item for Health Technology Reassessment at the 6th Health Technology Reassessment Committee (2020.6.12 - 6.19.) in 2020. , and the safety and effectiveness assessment results of the Colloidal reaction TTT [Chemical Reaction-Equipment Measurement] were finally deliberated at the 10th Health Technology Reassessment Committee (2020.10.16.) in 2020.

Assessment Method

The safety and effectiveness assessment of the colloidal reaction TTT [Chemical Reaction-Equipment Measurement] was performed through a systematic literature review.

All assessment methods were determined after deliberation by the “Colloidal reaction TTT [Chemical Reaction-Equipment Measurement] subcommittee (hereinafter referred to as the ‘sub-committee’) in consideration of the assessment purpose. The key question in the assessment is ‘Is it safe and effective to evaluate liver function through colloidal reaction in patients with (suspected) liver disease?’.

For the literature search, three overseas and five domestic databases were used, and two reviewers independently selected them according to the literature inclusion and exclusion criteria. The risk assessment 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. If there was any disagreement, it was planned to be discussed with a third party, but there was no disagreement. For data analysis, quantitative analysis was not possible, so a qualitative review was applied.

Assessment Results

The safety and effectiveness of Colloidal reaction TTT [Chemical Reaction-Equipment Measurement] were evaluated based on a total of 6 articles (6 overseas studies; 5 case-control studies, 1 case study). For interventional testing, the Maclagan, Shank-Hoagland, and Reinhold methods were specifically used. The baseline values were 4, 4.7, 5, 5.2, and 15 units, which differed for each literature.

Safety

The safety of colloidal reaction TTT [Chemical Reaction-Equipment Measurement] is an in vitro test that uses a patient's sample. Since the test does not directly harm the patient other than the sample collection process, it was evaluated that there is no problem in safety.

Effectiveness

The effectiveness of colloidal reaction TTT [Chemical Reaction-Equipment Measurement] was evaluated as an indicator of diagnostic accuracy, correlation with comparative tests, and relevance to disease, but there was no literature reporting diagnostic accuracy and correlation with comparative tests.

Thymol turbidity values were compared with healthy or patient controls in 5 out of 6 cases reporting relevance to disease. Of these, only two articles (one in comparison with the healthy control group and the other with the patient control group) reported statistically significant differences, and the other three articles did not report statistical significance. The remaining 1 article compared the usefulness of a total of 10 tests, including interventional tests, for liver disease patients. As a result, the discriminatory power of the interventional test was reported as the lowest among the tests included in the study.

Conclusion and Suggestions

Therefore, based on the literature basis, the subcommittee made the following recommendations.

Colloidal reaction TTT [Chemical Reaction-Equipment Measurement] does not directly harm patients other than the sample collection process, so there is no safety problem. However, it was judged as an invalid technology because there are no documents reporting the correlation with diagnostic accuracy and comparative tests, which are the main outcome indicators and it did not report consistent results even in the literature reporting the relationship with the disease.

In addition, this test is not used clinically, but the total protein test and albumin test are used as tests to evaluate liver function. There are a number of tests evaluating liver function in the current health insurance care benefit list, and the opinion was that there would be no clinical problems if the use of this technology was not recommended.

“Colloidal reaction TTT [Chemical Reaction-Equipment Measurement]” does not directly harm patients other than the sample collection process and there is no safety problem, but the literature reporting the correlation with diagnostic accuracy and comparative tests, which are the main outcome indicators, was not confirmed and the literature reporting the correlation with the disease did not report consistent results. Therefore, The Health Technology Reassessment Committee deliberated that it was not recommended due to lack of effectiveness in accordance with Article 4, Paragraph 10 of the Management Guidelines for the Health Technology Reassessment Project (2020. 11. 5.).

Key Words

Colloidal reaction, Thymol turbidity test, Safety, Effectiveness