



2020 Health Technology Reassessment Report

TBPE Assay

(TetraBromoPhenolphthalein Ethylester)

Summary

Background of Assessment

TBPE (TetraBromoPhenolphthalein Ethylester) assay is an in vitro diagnostic test performed for the purpose of screening narcotics. It is a colorimetric screening test that visually reads color changes by adding a TBPE reagent, which binds to specific structures (amines, etc.) of drugs.

The relevant health technology is a topic developed through internal monitoring and was regarded as a low-value or obsolete technology through the gathering of opinions of the Korean Society for Laboratory Medicine. It was selected as a Health Technology Reassessment agenda at the 6th Health Technology Reassessment Committee (2020.06.12.-19., written review) in 2020, and the safety and effectiveness evaluation results of the TBPE assay were finally reviewed at the 10th Health Technology Reassessment Committee (2020.10.16.) in 2020.

Assessment Method

Safety and effectiveness evaluation of the TBPE assay was performed through a systematic literature review. All evaluation methods were determined after deliberation by the "TBPE assay sub-committee (hereinafter referred to as 'subcommittee') in consideration of the research purpose. A key question in the evaluation was "Is the TBPE assay clinically safe and effective for screening narcotics (methamphetamine, etc.)?".

For the systematic literature review, the literature search, literature selection, data extraction, risk of bias assessment, and data analysis were performed according to the manual published by the National Evidence-based Healthcare Collaborating Agency (Soo-young Kim et al., 2011).

Assessment Results

Selection result of literature

The safety and effectiveness of the TBPE assay were evaluated based on a total of one literature. One selected document (Choi et al., 1993) is a study conducted in Korea and published in 1993. It performed screening tests and reported diagnostic accuracy on 442 urine samples obtained from athletes and police station drug abuse suspects who had been tested for doping to evaluate the

newly developed TBPE on-site test device.

Safety

The one selected document did not report the study results related to the safety of the TBPE assay.

Effectiveness

One selected study reported some results related to diagnostic accuracy. The false-positive rate of the fluorescence polarization immunoassay was 2.0%, whereas it was 10-15% for the TBPE assay. Also, when a negative sample in the TBPE assay was confirmed by a definitive test (GC/NPD), there was no sample containing methamphetamine or amphetamine (false negative 0%).

Conclusion and Suggestions

One document was finally selected through a systematic literature review. The TBPE assay for the screening narcotics could not confirm the evidence related to safety, but it was assumed that there would be no safety problem as an in vitro diagnostic method. In terms of effectiveness, the false positives of the TBPE assay were 15% and the false negatives were 0%, but the false positives of the fluorescence polarization immunoassay were only 2%. It was confirmed that the diagnostic accuracy was lower than that of the comparative test. Additionally, the detection limit and accuracy of the TBPE assay were not verified, and it was confirmed that this test was developed more than 20 years ago and is rarely used in developed countries. In Korea, it has been confirmed that it is used for recruitment physical examination, not for medical treatment.

Therefore, it was considered that there would be no problem in the safety of the TBPE assay for the screening narcotics as an in vitro diagnostic method, but it was evaluated as a test method with limited effectiveness due to low diagnostic accuracy.

The Health Technology Reassessment Committee reviewed the "TBPE assay" as follows based on the subcommittee review results (2020.10.16.). The Health Technology Reassessment Committee deliberated that the TBPE assay was not recommended (Recommendation Grade II) for the purpose of screening narcotics.

Key Words

Narcotics, Screening test, TetraBromoPhenolphthalein Ethylester, TBPE