2019 Health Technology Reassessment Report

Safety and Effectiveness Assessment of Progesterone Receptor Testing [EIA]

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Summary

□ Background

The Korea National Evidence-based Healthcare Collaborating Agency (NECA) runs a program to reassess items for which decision-making on preliminary coverage is scheduled for 2020, following a request by the Health Insurance Review & Assessment Service (HIRA). In this study, a safety and effectiveness reassessment of "Progesterone Receptor Testing [enzyme immunoassay, EIA],” an immunoassay method used in breast cancer hormone receptor testing, was performed.

□ Committee operation

A subcommittee of 8 members met once and examined the report over approximately 4 months from May through August 2019.

The Health Technology Reassessment Committee conducted the final review of the assessment results of the progesterone receptor testing (EIA) during the 2019 2nd committee meeting (October 11, 2019) and made a final decision on the grade of recommendation for the said technology during the 4th committee meeting (December 13, 2019).

□ Methods

The subcommittee expressed that it would be unnecessary to conduct a systematic review to compare the safety and effectiveness of the said technology and the currently used testing methods because it was replaced with other testing methods approximately 20 years ago due to the hassle associated with conducting the test and the risk associated with using radioactive material. Accordingly, in this report, the information on EIA in progesterone receptor testing was summarized based on a review of the current literature relevant to the methods of progesterone receptor testing in breast cancer patients as well as the details of the guidelines for hormone receptor tests for breast cancer. Additionally, the opinions of academic societies and experts were sought to understand the current domestic trends of EIA in progesterone receptor testing.

□ Results

Clinical practice guidelines developed outside Korea

A review of the clinical practice guidelines developed outside South Korea revealed that a majority described progesterone receptor testing based on immunohistochemistry (IHC) rather than EIA as the standard testing method. The descriptions of EIA were not found in most clinical practice guidelines. In an article (Ontario, Canada, 2012), it was recommended that IHC should replace all other testing methods, including EIA.

Previous health technology assessment report and systematic review

In a systematic review article on IHC, the committee found some comparisons involving EIA. The article reported that progesterone testing based on IHC, compared with EIA, predicted patient response to hormone therapy more consistently and predicted disease-free survival rate more accurately.

Literature comparing EIA and other testing methods

To examine the current literature on EIA in progesterone receptor testing in breast cancer patients, 1,859 articles were extracted from 2 foreign data sources. Of those, 68 articles reported on the use of the EIA method in progesterone receptor testing in breast cancer patients. Nineteen of those compared the EIA with other progesterone receptor testing methods, most of which were published before 2000; 4 were published after 2000. None of the articles were published after 2007.

Studies published in the 1990s compared the progesterone receptor levels measured using EIA and the dextran-coated charcoal method (DCC) and found that the correlation and agreement between the methods were relatively high. However, as other testing methods were developed during and after the 2000s, IHC is currently commonly used to determine the statuses of the estrogen receptor (ER) and the progesterone receptor (PR). It is consistently reported that IHC is superior to EIA.

Opinions of experts and academic societies

The subcommittee's clinical experts stated that progesterone receptor testing using EIA is difficult to perform; measurements do not involve only the tumor but also the

surrounding normal tissue. They also stated that the test-retest reproducibility is low and it is not currently used in practice, although it may be used for experimental purposes. Additionally, they stated that IHC is the current standard for measuring the status of the ER and the PR in breast cancer patients.

Relevant academic societies were contacted about the current use of hormone receptor testing methods. The Korean Society of Pathologists confirmed that EIA "is not currently used and it has been replaced with IHC."

□ Conclusion

Considering the timeline of the study, this study summarized the evidence in the literature by reviewing the guidelines developed outside South Korea for progesterone receptor testing based on EIA in breast cancer patients, other relevant literature, and the opinions of clinical experts and academic societies.

The reassessment of Progesterone Receptor-EIA (No-284), a method used to test the status of hormone receptors in breast cancer patients that is not currently covered by the national health insurance, showed the following. In the literature review, articles comparing EIA and other testing methods published after 2007 were not found. In addition, experts and relevant academic societies confirmed that EIA is not currently used to test the status of the progesterone receptor.

Based on a comprehensive review of the literature and guidelines published within and outside Korea and the opinions of academic societies, the subcommittee determined that IHC is a clinically useful progesterone receptor testing method for breast cancer and the current standard of practice.

The Health Technology Reassessment Committee does not recommend the use of EIA for progesterone receptor testing in breast cancer patients (Grade of Recommendation: II).