2019 Health Technology Reassessment Report

Safety and Effectiveness Assessment of Breast Cancer Receptor Testing [RIA]

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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, radioimmunoassay (RIA), an immunoassay method used in hormone receptor testing for breast cancer, was reassessed.

□ 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 RIA use in breast cancer receptor testing 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 determined that the said technology had already been replaced with other technologies for approximately 20 years due to the hassle and the risk of using radioactive material. Currently, the technology is not used, and the subcommittee expressed that it would be unnecessary to conduct a systematic review of the literature comparing the safety and effectiveness of RIA and currently existing technologies. Accordingly, in this report, information on RIA use in breast cancer hormone receptor testing was summarized based on the reviews of various studies on RIA and the current guidelines for hormone receptor testing in breast cancer.

□ Results

Current literature on RIA

To examine the current literature on hormone receptor testing methods in breast cancer patients, 1,859 articles were extracted from 2 foreign data sources. Of those, a single article included information on the use of RIA in hormone receptor testing for breast cancer. The article, published in 1981, indicated the methods for quantifying the estrogen receptor value using RIA, but it did not compare it with other testing methods.

Clinical evidence in and outside of Korea

A review of clinical practice guidelines developed outside South Korea showed that most guidelines described hormone receptor testing based on immunohistochemistry (IHC) and not RIA.

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

□ Conclusion

A reassessment of Estrogen Receptor, Progesterone Receptor-RIA (No-281), a method used to test the status of the hormone receptor in breast cancer patients was performed; it is currently not covered by the national health insurance. A literature review revealed that no article compared the said technology with other testing methods. The said technology was replaced with other testing methods approximately 20 years ago due to the hassle, the risk of using radioactive material, and low test accuracy and it is believed that this accounts for the aforementioned lack of articles.

Based on a comprehensive evaluation of the guidelines and comparative literature on testing methods inside and outside Korea and the opinions of Korean academic societies of clinicians, it was determined that HIS is the standard for hormone receptor testing for breast cancer.

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