2019 Health Technology Reassessment Report

Safety and Effectiveness Assesment of Estrogen Receptor Testing [EIA]

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Summary

□ Background

The Korea National Evidence-based Healthcare Collaborating Agency (NECA) operates health technology reassessment program to assess technology for which a decision on preliminary coverage was planned in 2020. In this study, the "Estrogen Receptor Testing [enzyme immunoassay, EIA]" was assessed for safety and effectiveness.

□ Committee operation

A reassessment subcommittee composed of 8 members carried out 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 reassessment results of EIA (a testing method used in estrogen receptor testing for breast cancer) during the 2019 2nd committee meeting (October 11, 2019) and made a final decision on the grade of recommendation during the committee meeting (December 13, 2019).

□ Methods

The reassessment subcommittee determined that although the EIA had been used in some institutions for experimental purposes, it was unnecessary to make an assessment through a systematic review because it was infrequently used and had not been utilized since the early 1990s. Accordingly, the evidence was summarized in this study based on the reviews of the guidelines for estrogen receptor testing in breast cancer patients and relevant literature.

□ Results

Clinical practice guidelines

A review of the clinical practice guidelines revealed that a majority described estrogen receptor testing based on immunohistochemistry (IHC) rather than EIA. In most clinical practice guidelines, the descriptions of EIA were not found. In one literature (Ontario, Canada, 2012), it was recommended that immunohistochemical tests should be used in place of all test methods such as enzyme immunological tests.

Previous health technology assessment report and systematic review

Although the prior medical technology **assessment** report could not be confirmed, a systematic literature review study on immunohistochemistry (Nofech-Mozes et al., 2012) was able to confirm some comparisons with enzyme immunological tests.

The article reported that compared with EIA, estrogen testing based on IHC predicted patient response to hormone therapy more consistently and provided more accurate prognostic indices including overall survival rate.

Current literature

A total of 40 literatures were selected as a result of a review of related literature on the estrogen receptor test (EIA) in breast cancer patients. Most of the literature was published before 2000 (n=34), and in the sixth literature published in the 2000s, the last literature was published in 2007. As a result of reviewing six documents published since 2000, all were research documents comparing EIA and IHC. The more recent literature, the better the immunohistochemistry test was reported than the enzyme immunological test.

Opinions of experts and academic societies

The reassessment subcommittee's clinical experts stated that estrogen receptor testing using EIA requires a biopsy of breast tissue or cell lines and it is not utilized because it is difficult to perform; the surrounding normal tissue, and not only the tumor, could be included in the measurement, and the reproducibility is very low. Additionally, they stated that although EIA was used in the past for experimental purposes, it is outdated, and there are superior testing methods such as HIA.

The clinical experts expressed that estrogen receptor testing using EIA has clear disadvantages, such as the need to use fresh frozen tissue and the inclusion of

surrounding normal tissue in the measurement in addition to the tumor, and it has been replaced with IHC.

□ Conclusion

This study summarized the evidence in the clinical guidelines on estrogen receptor testing based on EIA in breast cancer patients and relevant literature, as well as the opinions of clinical experts and academic societies.

The reassessment performed on Estrogen Receptor-EIA (No-283), a method used to test the status of the hormone receptor in breast cancer patients and currently not covered by the national health insurance, showed the following. In the literature review, articles comparing EIA with other testing methods have not been published for over a decade since 2007. In addition, experts and academic societies confirmed that estrogen receptor testing based on EIA is not utilized currently.

Based on a comprehensive assessment of the literature and clinical guidelines and expert opinions, the reassessment subcommittee determined that IHC is a clinically useful estrogen receptor testing method for breast cancer, and it is regarded as the current standard of practice.

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