2019 Health Technology Reassessment Report

Safety and Effectiveness Assessment of Polyamine

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Summary

□ Background

"Polyamine (classification ID No 289)" is used to detect polyamine, a tumor marker extensively detected in the urine of patients with solid cancers (such as cancer in the digestive system, lung cancer, breast cancer, ovarian cancer, and prostate cancer) or blood cancers (such as leukemia and malignant lymphoma). The technology was added to the no-coverage list on May 1, 2001. The Korea Health Insurance Review and Assessment Service (HIRA) sought the opinions of relevant academic societies (associations) on changing the coverage status of the items to preliminary coverage listed in the no-coverage list before the introduction of the Innovative Health Technology Assessment System. Subsequently, the HIRA requested the Korea National Evidence-based Healthcare Collaborating Agency (NECA) to perform a safety and effectiveness assessment of the 19 items for which the relevant academic societies (associations) recommended safety and effectiveness assessment. "Polyamine" was one of the 19 items.

□ Committee operation

A subcommittee composed of 6 members held a total of 4 meetings to assess the said technology within 5 months until August 31, 2019, and presented the review results. During the 2019 Health Technology Reassessment Committee meeting (December 13, 2019), the assessment results on "Polyamine" safety and effectiveness were reviewed.

□ Purposes and Methods

I. Purposes

"Polyamine" is a test used to detect polyamine in urine specimens in patients with esophageal cancer, stomach cancer, liver cancer, pancreatic cancer, colon cancer, rectal cancer, lung cancer, breast cancer, cervical cancer/uterine cervix carcinoma,

ovarian cancer, prostate cancer, leukemia, and malignant lymphoma. The purpose of this report was to assess the safety and effectiveness of the said technology.

II. Methods

The safety and effectiveness of the said test were assessed via a systematic review. A literature search was performed using 5 domestic databases, including KoreaMed, and 3 foreign databases (Ovid-MEDLINE, Ovid-EMBASE, and Cochrane Library). A total of 1,098 articles were obtained from the search, which used keywords such as neoplasm, cancer, and urinary polyamine. Of those, 1,074 articles (including 230 duplicates) were excluded and 24 (6 Korean and 18 foreign articles) were finally included in the review.

The subcommittee and 2 assessors independently performed the literature review and article search using an application based on the selection criteria and the evaluation of the quality of articles. Article quality was evaluated using QUADAS-2.

□ Results

A total of 24 articles were reviewed to assess the safety and effectiveness of the said technology. All of the articles were diagnostic accuracy studies.

I. Safety

None of the articles reported the safety of urine polyamine test. Because it is an ex-vivo diagnostic test using urine specimens, it was determined that safety would not be an issue.

II. Effectiveness

All 24 articles reported diagnostic accuracy. The sensitivities and specificities reported in the articles varied widely depending on the cancer type as well as the urine polyamine test item.

For the differential diagnosis of benign tumors and cancer, the ranges of diagnostic accuracy index values like sensitivity and specificity were wide across the articles, even for the same cancer type. The range of sensitivity was 12.5-87.5% for esophageal cancer, 12.5-87.5% for stomach cancer, 21.4-100.0% for liver cancer, 45.0-93.4% for pancreatic cancer, 23.1-92.1% for colorectal cancer, 25.0-100.0% for lung cancer, 0-33.6% for breast cancer, 37.0-51.0% for uterine cervix carcinoma, 10.5-100% for ovarian cancer, 72.2-73.3% for prostate cancer, and 25-100% for leukemia. The specificities were 13.1-93.2% for esophagus cancer, 13.1-93.2% for stomach cancer, 85.2-93.2% for liver cancer, 13.1-88.5% for pancreatic cancer, 13.1-93.2% for colorectal cancer, 32.0-88.5% for lung cancer, 0-100% for breast cancer, and 76.9-93.3% for prostate cancer.

For the differential diagnoses for normal and cancer patients, the sensitivities were 37.5% for esophagus cancer, 41.1-72.7% for stomach cancer, 76.5% for liver cancer, 100% for pancreatic cancer, 60.0-91.3% for colon and colorectal cancers, 100% for lung cancer, and 64.9-100% for ovarian cancer. The specificities were 100% for esophagus cancer, 73.3-100% for stomach cancer, 100% for liver cancer, 100% for pancreatic cancer, 73.3-100% for colon and colorectal cancers, 73.3% for lung cancer, and 4.8-61.9% for ovarian cancer.

Ten articles reported the correlations with comparison tests. The reported comparison tests were CA-19-9 for stomach cancer, AFP for liver cancer, CA-19-9 and CA-125 for pancreatic cancer, CEA and CA-19-9 for colorectal cancer, SCCA for uterine cervix carcinoma, and PSA for prostate cancer. The articles reported that the correlations between the outcomes of the urine polyamine test and a comparison test was very low or did not reach significance.

The impact of the urine polyamine test on healthcare outcomes, such as a change in treatment approach, was not reported in any of the articles.

□ Conclusion

Based on the current evidence found in the literature, the Polyamine subcommittee presented the following assessment results.

The systematic review showed that no article reported the safety of "Polyamine," and the subcommittee determined that safety is not an issue for the test.

The effectiveness, diagnostic accuracy, correlation with comparison tests, and impact on healthcare outcomes were evaluated using 24 articles. Diagnostic accuracy widely varied depending on cancer type as well as the researchers. The correlation between the test and a comparison test was low or did not reach significance. None of the articles reported the test's impact on healthcare outcomes such as a change in the treatment approach. In addition, the subcommittee did not find any recommendations for the technology in the clinical practice guidelines inside and outside Korea. Based on the findings, the subcommittee determined that the effectiveness of "Polyamine" is very low.

Based on the "Polyamine" subcommittee's review results, the Health Technology Reassessment Committee made the following decision (December 13, 2019).

The Health Technology Reassessment Committee does not recommend the use of "Polyamine" for diagnosis, patient follow-up, and prognosis evaluation for solid cancers (such as the esophagus, stomach, liver, pancreatic, colon, rectal, lung, breast, uterus/uterine cervix, ovarian, and prostate cancers) or blood cancers (leukemia and malignant lymphoma) (Grade of recommendation - II).