2019 Health Technology Reassessment Report

Safety and Effectiveness Assesment of Digital Breast Tomosynthesis

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Abstract (English)

□ Assessment background

Digital breast tomosynthesis (DBT) is a test method for screening and diagnosing breast cancer by synthesizing 3D images based on X-ray images from multiple angles for early detection of breast cancer in women.

This health technology was recognized as a test for screening or diagnosing breast cancer in follow-up patients and patients with abnormal findings on mammography through new health technology assessment in 2012 and was subsequently registered as a non-coverage item in 2014. The Ministry of Health and Welfare is the process of changing non-coverage items into items covered by insurance and providing evidence data for 2020 insurance coverage decision-making by updating the treatment efficacy of this technology.

□ Committee operation

The subcommittee, consisting of a total of five members recommended by clinical professional academies, held three subcommittee sessions over approximately four months up to August 31, 2019 and played an advisory role by participating in all assessments, including review of systematic literature review protocol, article selection and exclusion criteria, results synthesis, risk of bias assessment, and derivation of conclusions. In 2019 (October 11), the Health Technology Reassessment Committee conducted the final review on the clinical safety and efficacy assessment results of DBT.

□ Assessment objectives and methods

DBT safety and efficacy assessment followed the systematic literature review

protocol for new health technology assessment previously assessed, but the scope and content were confirmed by reaching a consensus of the subcommittee. For systematic literature review, five Korean and three foreign databases were searched. Two reviewers independently screened and selected the articles according to the selection and exclusion criteria. Risk of bias assessment was performed independently by two reviewers using QUADAS-2 until an agreement was reached. Data were extracted independently by two reviewers using pre-determined format. If there was a disagreement between the reviewers, such cases were discussed with a third party to reach an agreement. Meta-analysis was performed when quantitative analysis was possible and qualitative review was applied when otherwise.

Patients	▪ Follow-up patients and patients with abnormal findings on mammography
Index test	▪ Digital breast tomosynthesis (DBT)
Reference tests	▪ Histopathological examination ▪ Follow-up examination
Comparators	▪ Digital mammography ▪ Digital spot compression view
Outcomes	▪ Safety - Radiation exposure level ▪ Efficacy - Recall rate - Diagnostic accuracy - Disease detection rate

□ Assessment results

As a result of updated systematic literature review for reassessment of DBT safety and efficacy, a total of 32 articles were selected.

The safety of the same test was assessed by the amount of radiation exposure identified in four studies as a major indicator and the difference with the comparator test was –2.30mGy~1.68mGy, showing that the average amount of radiation exposure was similar between the two tests.

The efficacy of the same test was assessed by diagnostic accuracy, recall rate, and disease detection rate in 31 articles and the results were compared to those of digital mammography. The pooled sensitivity and specificity of this test identified in 24 articles included in the meta-analysis were 0.92 (95%CI 0.88-0.94) and 0.85 (95%CI 0.77-0.91), respectively, which showed statistically significant differences with the comparator test showing pooled sensitivity and specificity of 0.82 (95%CI 0.74-0.87) and 0.83 (95%CI 0.73-0.90), respectively (p=0.01). Moreover, the levels of pooled likelihood ratio and diagnostic odds ratio were high. When diagnostic accuracy was identified by varying the patient characteristics and characteristics of the interventional tests, the results were similar to the overall diagnostic accuracy and there were no factors that affected heterogeneity. Moreover, the results of sensitivity analysis with consideration for the sample size, patient group exclusion, level of diagnostic accuracy, and positive test criteria were consistently similar. The disease detection rate of the same test identified in 24 articles was statistically significantly higher by 9% than the comparator test (RR=1.09, 95% CI 1.04-1.15, I^2=20.0%). The recall rate calculated by 24 articles did not show statistically significant difference as compared to the comparator test, but heterogeneity among the articles was very high (I^2=91.0%).

□ Conclusions

The DBT subcommittee proposed the following based on currently available assessment results.

When the safety and efficacy of DBT in follow-up patients and patients with abnormal findings on mammography were assessed based on 32 articles, there was no evidence that the safety of the same test is more harmful than digital mammography, the comparator test. Meanwhile, the diagnostic accuracy and disease detection rate were consistently high and there was no difference in recall rate. Such findings were consistent with results reported in existing literature.

Based on such literary evidence, the subcommittee determined that DBT is a safety and effective technology with higher diagnostic accuracy and disease detection rate than digital mammography, the conventional test method, for screening and diagnosing breast cancer in follow-up patients and patients with abnormal findings on mammography.

The Health Technology Reassessment Committee reviewed and determined that the findings of the subcommittee on DBT are valid (October 11, 2019).