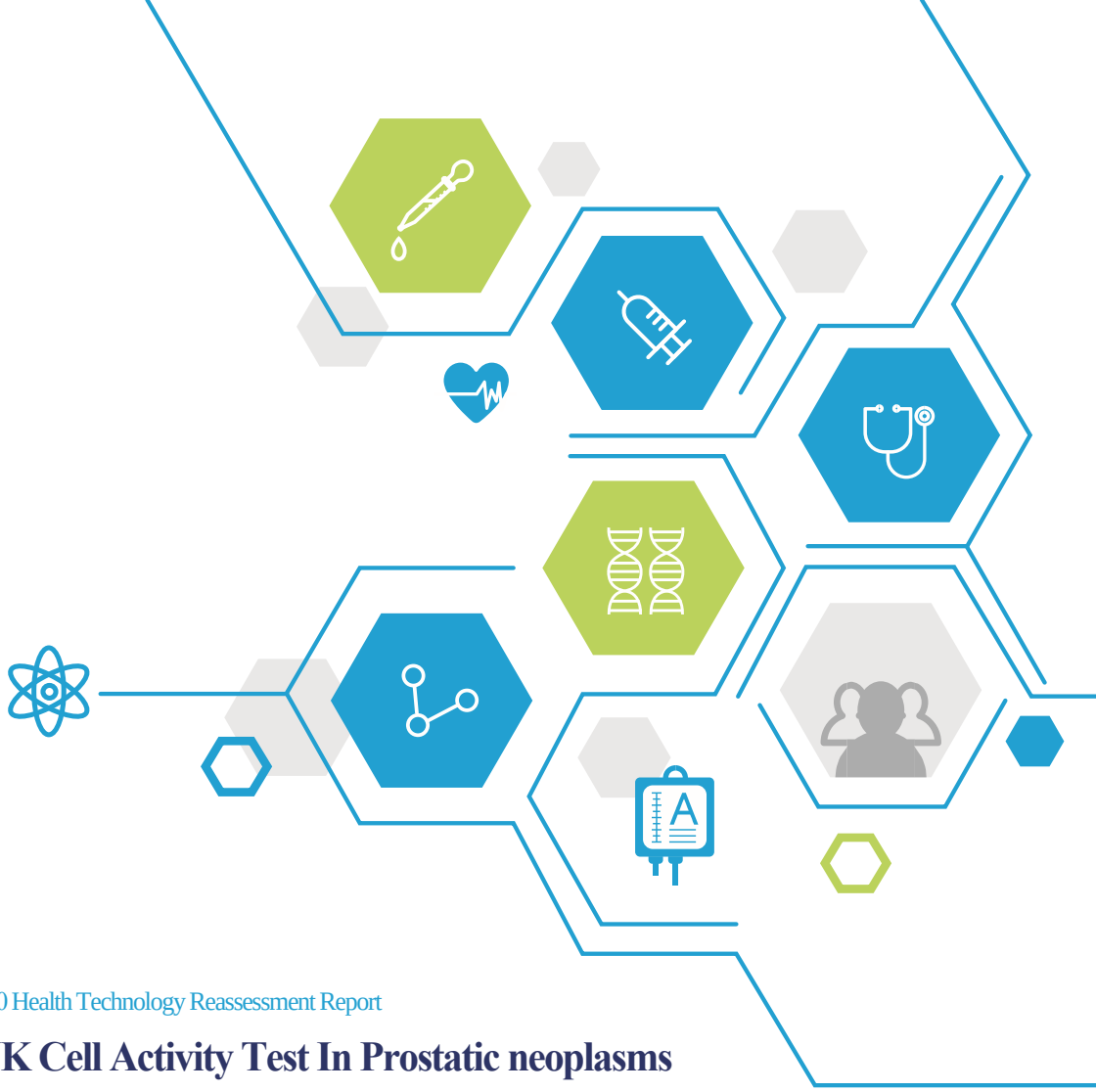

2020 Health Technology Reassessment Report

NK Cell Activity Test In Prostatic neoplasms [High-quality immunoassay]

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Summary

Background of Assessment

The NK cell activity test [high-quality immunoassay] is a test performed for patients with prostatic neoplasms to check their condition and monitor the progress of treatment by measuring the interferon-gamma (IFN-γ) using enzyme immunoassay after incubation of the patient's blood in a tube containing NK cell-active substances.

At the 4th New Health Technology Assessment Committee (2014.04.25.) in 2014, this technology was reviewed as a technology with safety and effectiveness, the results of the new health technology assessment were noticed (No. 2014-89). It was registered as a selective benefit (Ministry of Health and Welfare Notice No. 2016-104). Afterward, the Health Insurance Review and Assessment Service requested a re-evaluation to derive the necessary data for decision-making, such as determining the feasibility of applying the benefit to the technology. Accordingly, a subcommittee was formed for this technology to evaluate safety and effectiveness.

Committee’s Operation

The subcommittee consisted of a total of 11 members and held a total of three subcommittee meetings (2 times in-person,1 time written meeting) for about three months May 27, 2020, to August 31, 2020. Based on the opinions of the subcommittee, the final deliberation was conducted on the re-assessment results of the safety and effectiveness of the NK cell activity test [high-quality immunoassay] in prostatic neoplasms at the 10th Health Technology Reassessment Committee (2020.10.16.).

Purpose and Method of Assessment

It is intended to re-assess the medical and scientific evidence for clinical safety and effectiveness by conducting a systematic literature review when the NK cell activity test [high-quality immunoassay] is performed to check the patients' condition and monitor the progress of treatment in patients with prostatic neoplasms.

Assessment Results

A total of 6 pieces of literature were selected for this assessment (5 cross-sectional studies, 1 patient control group). By subject, there were 5 patients with suspected prostatic neoplasms, 1 patient with prostatic neoplasms, and 1 patient in a healthy control group. The test methods used in all 6 documents were the ELISA method.

The subcommittee discussed whether to include literature performed on patients with suspected prostatic neoplasms in the assessment because this test is performed on actual prostatic neoplasms patients. As a result, since the evidence related to this test was insufficient, it was decided to include all the literature that performed this technology in the assessment to check the current literature level. In 4 out of 6 articles, the diagnostic accuracy for the classification of prostatic neoplasms and the diagnosis accuracy related to the classification between the groups with high Gleason grade prostatic neoplasms and low Gleason grade prostatic neoplasms and no prostatic neoplasms were reported. However, the subcommittee excluded it from the analysis of the results because of the opinion that it was not suitable for this assessment since the contents did not meet the purpose of the test, which is to check the status through measurement of cellular immune activity and monitor the progress of treatment.

There were no literature reports on the safety of this test. Accordingly, the subcommittee was of the opinion that there was no problem with safety in carrying out other than blood collection since this test was performed in vitro by collecting blood.

For the effectiveness, the relevance to disease, disease severity, and monitoring of treatment progress were evaluated as the main indicators.

Regarding the relationship between disease and disease severity, the statistical significance or differences in NK activity according to disease severity (Gleason score or stage) between groups were reported in all six final selected documents by using the difference in NK cell activity between the group with prostatic neoplasms (or prostatic neoplasms patient) and the group without prostatic neoplasms (or healthy control group). In the study results, it was confirmed that the NK cell activity was significantly higher in the healthy control group compared to the prostatic neoplasms patient, but no significant difference was confirmed by the severity of the prostatic neoplasms. Some of the studies that suggested the odds ratio related to the diagnosis of prostatic neoplasms did not show any significant results.

Accordingly, the subcommittee was of the opinion that it was difficult to prove the effectiveness of the test based on the contents alone because effectiveness-related medical results did not fully explain the relationship between NK cell activity and prostatic neoplasms and the severity of prostate cancer, and insignificant results were found in the reported medical results.

In the case of treatment progress monitoring, as results of NK cell activity before and after prostate surgery, the results of comparing NK cell activity between groups showing positive and negative margins at the surgical site after surgery with PSA, and the results of confirming the biochemical recurrence-free survival rate in the group with a threshold of NK cell activity of 650 pg/ml or higher have been reported in one literature.

The subcommittee determined that the effectiveness of the test could not be verified because it is difficult to say that simply checking the result of measuring NK cell activity before and after surgery is useful in confirming the patient's condition or monitoring the progress of treatment and because the outcome of the recurrence-free survival rate is not statistically significant.

Conclusion and Suggestions

The NK cell activity test [high-quality immunoassay] subcommittee made the following recommendations based on the current assessment results.

NK cell activity test [high-quality immunoassay] is a test performed for patients with prostatic neoplasms to check the patient's condition and monitor the progress of treatment. Concerns about safety in performing the test are low, but there was an opinion that the safety and effectiveness of the technology could not be confirmed due to insufficient literature evidence.

The Health Technology Reassessment Committee reviewed the NK cell activity test [high-quality immunoassay] in patients with prostatic neoplasms as follows based on the subcommittee review results (10/16/2020).

NK cell activity test [high-quality immunoassay] is a test performed for patients with prostatic neoplasms to check the patient's condition and monitor the progress of treatment. It was judged as a technology that could not confirm the safety and effectiveness of the technology due to the lack of accumulated literature evidence to prove its safety and effectiveness.

Therefore, the Health Technology Reassessment Committee decided not to recommend that NK cell activity test [high-quality immunoassay] be performed for patients with prostatic neoplasms to check the patient's condition and monitor the progress of treatment (Recommendation Grade II) (2020.10.16.).

Keywords

Prostatic neoplasms, Natural killer cell, Interferon-gamma