NECA-Health Technology Reassessment Project

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Health Technology Reassessment Report 2020

Sudomotor Function Test

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Summary Statement

Background

Sudomotor function indicator is a patch type tester for detecting dysfunction of peripheral and autonomic nervous systems by its color change. It is based on the idea of that when peripheral neuropathy occurs, sweat glands on the feet destroy first. This test is a medical technology publicly announced (a Ministry of Health and Administration Announcement #2018-50 (Mar. 26, 2018) as a non-payment item after the New Medical Technology Assessment in 2012.

'Sudomotor Function Test' was reviewed as safe and efficient medical technology for diagnosing diabetic peripheral neuropathy (Recommendation Grade C), and required further research due to a lack of study result for patient who has suspicious cardiovascular autonomic neuropathy(Recommendation Grade D) in the New Medical Technology Assessment in 2012 .

As a result of internal monitoring, it was decided that this medical technology should be re-assessed for its safety and effectiveness. Therefore, the technology was brought to the 8th Health Technology Reassessment Committee in 2020 for re-assessment, in an attempt to find the ground of efficient use of health and medical resources.

Comprised of 5 different sub-committee members (2 endocrinologists, 2 neurosurgeons, 1 evidence-based medicine specialist), the sub-committee for re-assessment of the technology (the "sub-committee") held three different review meetings starting at September 2020 and ended at February 2021. After that the final assessment regarding the re-assessment result and recommendation for grading was performed in the 3rd Health Technology Reassessment Committee in 2021 (Mar. 12, 2021).

Methodology

Systematic review was performed to re-assess the clinical safety and effectiveness of the technology - Sudomotor Function Test - in diagnosis of peripheral neuropathy in patient with Type 1 and Type 2 diabetes.

Three different international databases and five different domestic databases were used to select studies. Selection of studies based on the inclusion and exclusion criteria, and performed by two reviewers independently. The selected studies were screened by the sub-committee for confirmation.

These two reviewers reached a consensus in that they perform risk of bias assessment on a separate basis, using QUADAS-2. The collected data were meta-analyzed since they were adequate for quantitative analysis.

The Health Technology Reassessment Committee determined recommendation grade for the technology based on the discussions underwent by the sub-committee.

Result

A total of 20 studies (including 11 studies from the previous New Medical Technology Assessment in 2012) were systematically reviewed for assessment of safety and effectiveness of Sudomotor Function Test.

Safety

Safety of Sudomotor Function Test was assessed by the Test-related complications and side effects. Sudomotor Function Test involves attachment of a test patch to the sole to observe color change of the patch. As for potential side effects such as skin rash on the sole, no side effect was reported in any of 20 studies selected. Therefore, it is to say that the safety Sudomotor Function Test is confirmed.

Efficacy

The effectiveness of Sudomotor Function Test was assessed by i) diagnostic accuracy, ii) relevance to comparative study and iii) impact on the medical result (meaning change in treatment rate or treatment method).

While all 20 studies selected present accuracy of diagnosing diabetic neuropathy, the official diagnosis of such diagnosis varies by studies. Therefore based on the authorized purposes of medical device approved by the MFDS, diagnostic accuracy for Peripheral Neuropathy, such as Small fiber neuropathy (SFN), small fiber dysfunction (SFD) were analyzed separately. The rest of the diagnoses were analyzed within Peripheral Neuropathy

Out of the selected 20 studies, only 4 studies reported diagnostic accuracy of small fiber neuropathy (SFN), small fiber dysfunction (SFD). No study reported diagnostic accuracy of comparative study. As a result of meta analysis, diagnostic accuracy of small fiber neuropathy (SFN) and small fiber dysfunction (SFD) was, in integrated sensitivity, 0.81(95% CI: 0.52-0.95), in integrated specificity, 0.69(95% CI: 0.41-0.88), in integrated positive likelihood ratio, 2.7(95% CI: 1.2-6.1), in integrated negative likelihood ratio, 0.27(95% CI: 0.09-0.85) and, in integrated diagnostic odds ratio, 10(95% CI: 2-54).

All 20 studies reported diagnostic accuracy for other peripheral neuropathy. Out of the selected 20 studies, only 4 studies reported diagnostic accuracy on comparative studies (Vibration perception threshold (VPT), 10g-monofilament, VibraTip) (Gomez-Banoy et al., 2017; Aubert et al., 2013; Tentolouris et al., 2010; Papanas et al., 2008). As a result of meta analysis, diagnostic accuracy of such other peripheral neuropathy was, in integrated sensitivity, 0.87(95% CI: 0.82-0.92), in integrated specificity, 0.67(95% CI: 0.53-0.78), in integrated positive likelihood ratio, 2.7(95% CI: 1.8-3.9), in integrated negative likelihood ratio, 0.19(95% CI: 0.12-0.29) and, in integrated diagnostic odds ratio, 14(95% CI: 7-29).

Out of the selected 20 studies, only 2 studies reported diagnostic accuracy (foot ulcer, neuropathy) of VPT in comparison to Sudomotor Function Test (Tentolouris et al., 2010; Papanas et al., 2008).

As for the above-mentioned VPT, sensitivity, specificity, false positive rate, false negative rate and diagnostic accuracy were 78.9 - 85.4%, 67.6 - 85.9%, 14 - 32.2%, 14.3 - 21.1% and 79.9 - 81.8%, respectively, implying that the sensitivity and diagnostic accuracy were lower than those of Sudomotor Function Test (97.1 - 97.8%) (81.5 - 85.5%) and the specificity was higher than that of Sudomotor Function Test (49.3 - 67.1%).

Out of the selected 20 studies, only 2 studies reported diagnostic accuracy (peripheral neuropathy, foot ulcer) of 10g-Monofilament in comparison to Sudomotor Function Test (Aubert et al., 2013; Tentolouris et al., 2010). As for the above-mentioned 10g-Monofilament, sensitivity,

specificity, false positive rate, false negative rate and diagnostic accuracy were 57.4 - 67.7%, 86.3 - 94%, 5.9 - 14%, 32.3 - 43% and 66.2 - 90%, respectively, implying that the sensitivity was lower than those of Sudomotor Function Test (93.5 - 97.1%) and the specificity and diagnostic accuracy were higher than those of Sudomotor Function Test (23 - 49.3%) (34 - 81.5%).

Out of the selected 20 studies, only 1 study reported diagnostic accuracy (distal symmetrical polyneuropathy; DSPN) of VibraTip in comparison to Sudomotor Function Test (Gomez-Banoy et al., 2017). As for the above-mentioned DSPN, sensitivity, specificity, false positive rate, false negative rate and diagnostic accuracy were 54.1%, 91%, 8.69%, 45.8% and 81.7%, respectively, implying that the sensitivity was lower than those of Sudomotor Function Test (66.6%) and the specificity and diagnostic accuracy were higher than those of Sudomotor Function Test (63%) (64.5%).

None of the selected studies reported relevance of the technology to comparative studies. None of the selected studies reported change in treatment rate or treatment method, the criteria for assessing impact on the medical result.

Conclusion and Suggestion

The sub-committee suggests, based on the selected studies, as follows:

Considering that diagnostic peripheral neuropathy is determined by comprehensively taking into account a variety of clinical diagnostic results, Sudomotor Function Test is safe and effective when used in diagnosis of peripheral neuropathy in patient with Type 1 and Type 2 diabetes.

In the 3rd Health Technology Reassessment Committee in 2021 (Mar. 12, 2021), Sudomotor Function Test was considered safe as a result of reviewing potential side effects such as skin rash on the sole, meaning that it is effective in diagnosis of peripheral neuropathy in patient with Type 1 and Type 2 diabetes. Therefore, the Health Technology Reassessment Committee assessed that Sudomotor Function Test is safe and effective medical technology for detecting peripheral neuropathy in patient with Type 1 and Type 2 diabetes, and recommended (Recommendation Grade I-b).

Keywords

Diabetes mellitus, Sudomotor function indicator, Diabetic peripheral neuropathy