NECA-Health Technology Reassessment Project

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Health Technology Reassessment Report 2020

Laser Doppler Peripheral Vascular Disease Assessment with Pressure Cuff

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Summary Statement

Background

Laser Doppler peripheral vascular disease assessment with pressure cuff is performed to assist in evaluating and monitoring surgical treatments and therapeutic drug treatments in patients with critical limb ischemia, by non-invasively measuring the blood flow using the Laser Doppler Principle in monitoring blood flow abnormality and measuring the severity thereof. Reviewed for its safety and effectiveness in the 10th meeting of New Health Technology Assessment Committee in 2015, Laser Doppler peripheral vascular disease assessment with pressure cuff was registered as a new health technology as a non-benefit item.

In the 8th Health Technology Reassessment Committee in 2020 (Aug. 14, 2020), it was deliberated that the medical evidences of the safety and effectiveness of the technology - Laser Doppler peripheral vascular disease assessment with pressure cuff - was re-assessed and the grade of recommendation of the technology was determined by way of systematic literature to support decision-making for the efficient use of health and medical resources.

Methods

The medical evidences of the safety and effectiveness of the technology - Laser Doppler peripheral vascular disease assessment with pressure cuff - was re-assessed by way of systematic review. Taking into account the purpose of this study, the safety and effectiveness review was conducted by the competent sub-committee in charge of assessing Laser Doppler peripheral vascular disease assessment with pressure cuff (the “sub-committee”) and comprised of 8 different specialists (2 vascular surgeons, 2 thoracic surgeons, 1 orthopedic surgeon, 1 physiatrist, 1 radiologist, 1 evidence-based medicine specialist).

The key question of the above-mentioned systematic review was ‘Is Laser Doppler peripheral vascular disease assessment with pressure cuff clinically safe and effective to use in assessing and monitoring surgical treatment results and medication results in patients with critical limb ischemia?’. Based on the above-mentioned key question, three different international literature databases and five different domestic literature databases were referred to in selection of literatures to be reviewed, under literature inclusion and exclusion criteria and by two separate reviewers. These two separate reviewers reached a consensus in that they perform the risk of bias assessment on a separate basis, using RoBANS ver 2.0. Data extraction was also done by these two separate reviewers, also on a separate basis, using the pre-determined data extraction format. When they failed to reach a consensus, the third reviewer came into play for discussion. All data were analyzed qualitatively. The final grade of recommendation was determined by taking into account the review opinion of the sub-committee in the 3rd Health Technology Reassessment Committee in 2021.

Results

A total of 4 cohort studies were selected for re-assessment of Laser Doppler peripheral vascular disease assessment with pressure cuff - three of these studies regarding studies in patients with critical limb ischemia were included in the previous New Medical Technology Assessment and the remaining one study was published thereafter. The overall risk of bias for all these literatures was low.

Safety

No literature reported any index this study has set as safety indices for Laser Doppler peripheral vascular disease assessment with pressure cuff - side effects and adverse events, false negative results, and false positive results. The sub-committee determined that the technology - Laser Doppler peripheral vascular disease assessment with pressure cuff - non-invasively measures subcutaneous blood flow by means of laser derived from the sensor placed on the skin and by reading the numbers on the device and does not affect safety.

Effectiveness

The impact on the medical outcome of Laser Doppler peripheral vascular disease assessment with pressure cuff could not be assessed since none of the studies reported this outcome. In a study reporting the accuracy of treatment results, in assessing focal wound closure the accuracy of the index test (critical skin perfusion pressure: 40 mmHg) was 84% - quite similar to toe pressure (82%) and slightly higher than ankle pressure (71%) and transcutaneous oxygen pressure (79%). The relationship between the technology and treatment results was reported in one of the above-mentioned literatures. No statistically significant relationship between the technology and Rutherford's Classification for limb ischemia or the index test result (skin perfusion pressure) was observed. The relationship between the technology and expected prognoses was reported in two of the above-mentioned literatures, with one reporting the statistically significant relationship between the technology and amputation-free survival, non-existence of major side effects in lower limbs or wound closure. In another study, however, no statistically significant relationship between the technology and amputation-free survival, limb salvage rate or total survival rate was observed, given critical skin perfusion pressure at 40 mmHg. When critical skin perfusion pressure was given at the increase of 20 mmHg, the only index showing statistically significant relationship with the technology was amputation-free survival, meaning that no statistically significant relationship between the technology and limb salvage rate or total survival rate was observed.

Conclusion

The sub-committee, as a result of re-assessing Laser Doppler peripheral vascular disease assessment with pressure cuff suggested as follows:

The sub-committee determined that, despite safety of Laser Doppler peripheral vascular disease assessment with pressure cuff, the study design must be improved such that more objective critical skin perfusion pressure and generalizable evidences can be found and presented, since the relationship between the technology and skin perfusion pressure in additional study found after the New Medical Technology Assessment was inconsistent. In conclusion, despite safety of Laser Doppler peripheral vascular disease assessment with pressure cuff when used as an auxiliary means of assessing and monitoring treatment results in patients with critical limb ischemia, the technology's effectiveness after the New Medical Technology Assessment cannot be assessed.

The 3rd Health Technology Reassessment Committee in 2021 (Mar. 12, 2021) determined that despite safety of Laser Doppler peripheral vascular disease assessment with pressure cuff when used as an auxiliary means of assessing and monitoring treatment results in patients with critical limb ischemia, the technology's effectiveness after the New Medical Technology Assessment cannot be assessed, whereby the technology cannot be recommended (Grade of Recommendation II).

Keywords

Critical Limb Ischemia, Laser Doppler, Skin Perfusion Pressure, Safety, Effectiveness