2020 Health Technology Reassessment Report

Trigeminal Nerve Stimulation [with Implantable Pulse Generators]

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Summary

Background of Assessment

Trigeminal nerve stimulation [with implantable pulse generators] is a technology to improve pain through electrical stimulation by inserting electrodes into the trigeminal nerve area in patients with chronic intractable trigeminal neuropathy pain.

This technology was announced as a technology with safety and effectiveness in the new health technology assessment in 2009, and then was registered as a non-benefit service in 2010 (Ministry of Health and Welfare Notice No. 2010-4, 2010.3.29.). This technology was selected as a reassessment agenda through internal monitoring of the Health Technology Reassessment Project in 2020. At the 6th Health Technology Reassessment Committee in 2020 (June 12, 2020 - June 19, 2020), a subcommittee consisting of a total of 7 members (2 from the department of neurology, 2 from the department of neurosurgery, the department of anesthesiology and pain medicine, the department of rehabilitation medicine, the department of evidence-based medicine) on safety and effectiveness was deliberated to evaluate through systematic literature review. The final deliberation was made at the 12th Health Technology Reassessment Committee (2020.12.11.) in 2020.

Assessment Method

In this evaluation, a systematic literature review was performed to assess whether trigeminal nerve stimulation [with implantable pulse generators] is clinically safe and effective for patients with chronic intractable trigeminal neuropathic pain.

For the systematic literature review, the literature search was conducted in 5 domestic databases (KoreaMed, Korean Medical database, Academic Database, Korea Education and Research Information Service (KERIS), National Digital Science Links (NDSL)) and 3 foreign databases (Ovid MEDLINE, Ovid EMBASE, Cochrane Central Register of Controlled Trials) based on the above key questions. The application of the literature inclusion and exclusion criteria, data extraction, and risk of bias evaluation were all independently performed by two evaluators. For the risk of bias assessment, Cochrane's Risk of Bias was used for randomized studies, and the Risk of bias for nonrandomized studies (RoBANS) 2.0 Korean version was used for other non-randomized studies, depending on the study type. To evaluate the level of evidence in the literature, Grading of Recommendations Assessment, Development and Evaluation (GRADE) was used. In consideration of the subcommittee's review opinion, the Health

Technology Reassessment Committee presented the recommendation grade after final deliberation.

In this assessment, for safety, case studies and case reports were evaluated without limiting the number of study subjects in order to check all side effects and adverse events of the technology. For effectiveness, only studies with 10 or more subjects who had undergone permanent trigeminal nerve stimulation were included to increase the generalizability of the study results. However, studies in which safety was not mentioned among studies with 9 or fewer study subjects were excluded from the evaluation as the results of the study were inappropriate.

Assessment Results

A total of 24 studies were selected for evaluation, including 11 before-and-after studies and 15 case studies and case reports. Subjects included in the selected literature were patients with trigeminal neuropathic pain caused by various causes such as trauma, surgery, infection, etc. All of them were patients with chronic, intractable pain who did not respond to existing treatment and had electrodes inserted into the trigeminal nerve, such as the orbital nerve and mandibular nerve.

As a result of safety evaluation, infections (9 studies, 0-20.6%), wounds (8 studies, 4.3-25.0%), device-related side effects (13 studies, 2.9-50.0%), and neurological symptoms (11 studies, 4.8-33.3%) were confirmed in a total of 24 studies. Of these, in most cases of infection, re-implantation was performed after device removal and antibiotic treatment. Also, in most cases of wounds, reoperation or re-implantation was performed after removal of the device. It was reported that most of the device-related side effects are malfunctioning of the electrode, mechanical defects, and deviation of the electrode position, and the device replacement or reoperation has been conducted. In relation to neurological symptoms, ptosis, paresthesia, dull sensation, headache, temporary facial palsy, mild allodynia, and vertigo and tinnitus were confirmed.

Effectiveness assessment was evaluated using a total of 11 before-and-after studies, and most of the studies reported improved pain and reduced drug use. As for patient satisfaction, the proportion of patients who were moderately or more satisfied was reported to be 70% or more in 2 studies, and the quality of life was significantly improved in daily life and social activities as a result of 24 months of follow-up in 1 study. However, there was no significant improvement in the need for rest and sleep quality. As for employment change, it was reported in 1 study that 6 out of 8 patients were employed before the procedure, and the employment status changed to 7 people.

As for the level of evidence (GRADE evaluation), the high risk of bias was

considered for 'confounding ', 'measurement of the outcome, and ‘missing data' in some literature, and it was evaluated as 'Very Low'.

As a result of the safety review, the subcommittee was of the opinion that neurological problems were not considered to be a clinical problem at a minor level, but infection and device-related problems were confirmed at a relatively high level. Accordingly, it was determined that the procedure was performed under considerable caution and supervision in consideration of the possibility of infection and device-related problems resulting from the procedure, and that appropriate infection control was necessary after the procedure. As a result of the effectiveness review, this technology can help improve pain and reduce drug use for patients with chronic intractable trigeminal neuropathic pain whose pain cannot be controlled with conventional drug treatment or existing procedures. Therefore, even considering the possibility of device-related problems, it was judged as a technology necessary for clinical practice because the benefit it can bring to the patient is large. However, considering the limited level of evidence, it is necessary to continuously accumulate more evidence through well-designed studies.

Conclusion

The subcommittee made the following recommendations based on the current evaluation results.

Trigeminal nerve stimulation [with implantable pulse generators] helps to improve pain and reduce drug use when performed for pain relief in patients with chronic intractable trigeminal neuropathic pain whose pain cannot be controlled by conventional medications or existing procedures. It was judged to be a safe and effective technology because the benefit it can bring to the patient is large even if the possibility of infection and device-related problems arising from the procedure is considered. However, considering the limited level of evidence, there was an opinion that it is necessary to continuously accumulate more evidence through well-designed studies.

The Health Technology Reassessment Committee deliberated as follows based on the results of the subcommittee's review (December 11, 2020).

Trigeminal nerve stimulation [with implantable pulse generators] was deliberated as a safe and effective technology because it helps to improve pain and reduce drug use when it is performed for pain relief in patients with chronic intractable trigeminal neuropathic pain whose pain cannot be controlled by conventional medications or existing procedures and has a large benefit to the patient even when considering the possibility of infection and device-related problems arising from the procedure.

The Health Technology Reassessment Committee considered the use of trigeminal nerve stimulation [with implantable pulse generators] as a 'recommended' (recommendation grade: 1b) for pain relief in patients with chronic intractable trigeminal neuropathic pain whose pain could not be controlled with conventional treatment.