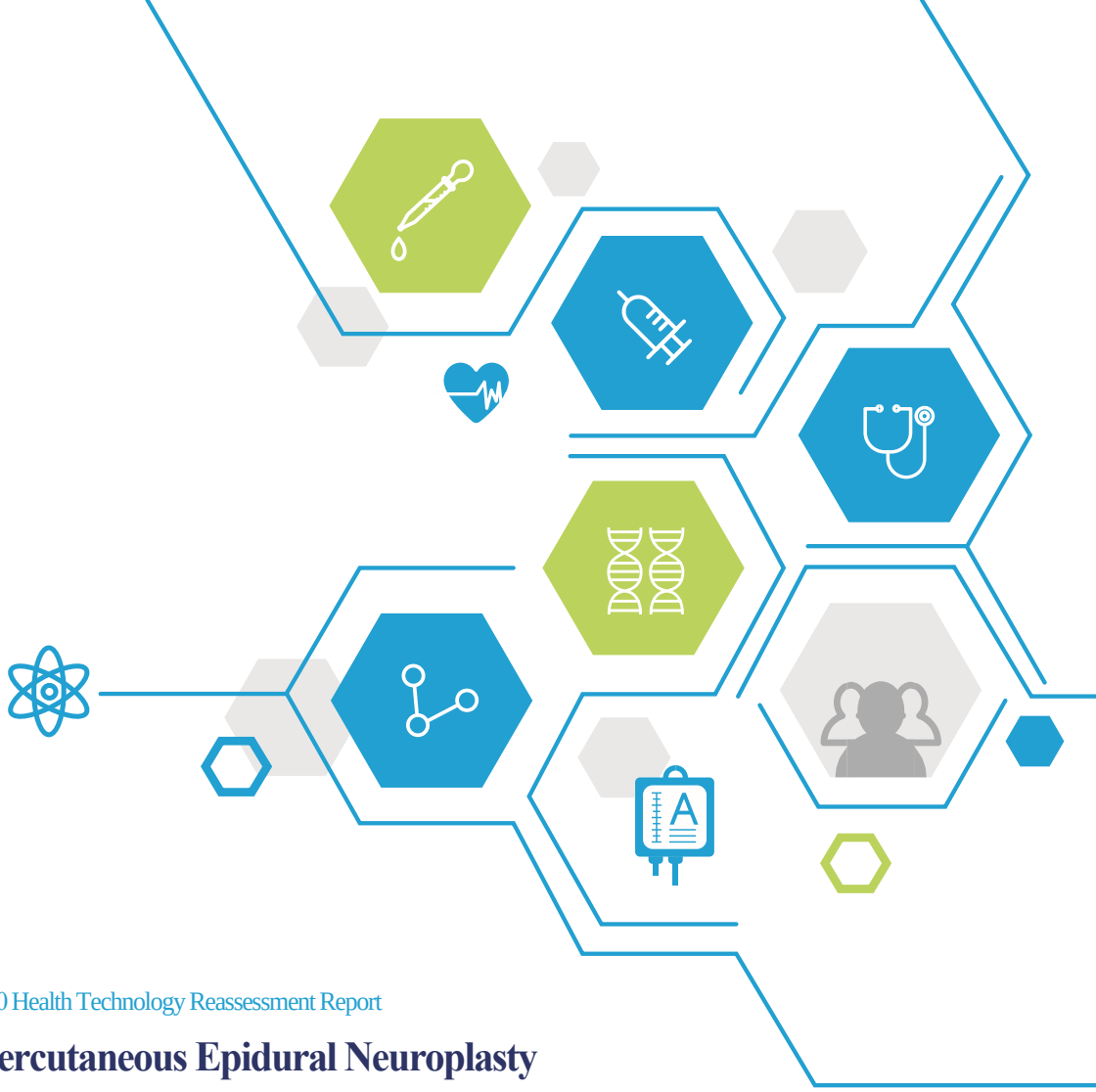

2020 Health Technology Reassessment Report

Percutaneous Epidural Neuroplasty

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Summary

Background of Assessment

Percutaneous epidural neuroplasty is a technique performed to reduce pain in patients with spinal pain. It is a procedure that percutaneously inserts a catheter for neuroplasty into the epidural space to remove adhesions in lesions of the epidural space and inject therapeutic drugs.

After the announcement of measures to strengthen health insurance coverage (August 2017), as the conversion to the reimbursement benefits from health non-insured benefits in the areas of 'spine, musculoskeletal system, and pain' was promoted in 2020, the need to review the feasibility of benefit conversion has been suggested since the neuroplasty surgery (endoscopic epidural neuroplasty, percutaneous epidural neuroplasty, percutaneous epidural neuroplasty with balloon catheter) has a large non-reimbursement scale and it is expected that various issues will arise when changing benefits.

Afterward, the Ministry of Health and Welfare requested the National Evidence-based Healthcare Collaborating Agency to re-evaluate four existing spinal-related practices/procedures (intradiscal electrothermal therapy, endoscopic epidural neuroplasty, percutaneous epidural neuroplasty, percutaneous epidural neuroplasty with balloon catheter) (January 2020). Accordingly, the clinical safety and effectiveness of percutaneous epidural neuroplasty were evaluated at the 2nd Health Technology Reassessment Committee (2020.2.14.) in 2020 after reviewing the evaluation protocol and subcommittee composition plan.

Assessment Method

In this assessment, a systematic literature review was performed to evaluate whether percutaneous epidural neuroplasty is clinically safe and effective for patients with spinal 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 evaluation, in the case of comparative treatment, to evaluate the effectiveness of interventional treatment, the treatment used in the existing reimbursement coverage was regarded as appropriate treatment and only studies compared with the corresponding comparative treatment (including placebo control group) were selected as literature for evaluation.

For this assessment, a subcommittee consisting of a total of 10 members (2 from the Department of Anesthesiology and Pain Medicine, 2 from Department of Neurosurgery, 2 Department of from Orthopedic Surgery, 1 from the Department of Radiology, 1 from the Department of Rehabilitation Medicine, 2 from the Evidence-Based Medicine)evaluated the literature basis for the safety and effectiveness of the technology through systematic literature review. At the 12th Health Technology Reassessment Committee (2020.12.11.) in 2020, the clinical safety and effectiveness assessment results of percutaneous epidural neuroplasty were finally reviewed.

Assessment Results

A total of 11 articles of literature were selected for assessment, compared with conservative treatment (2 articles), placebo (1 article), and epidural nerve block (8 articles). For the patient characteristics, patients with cervical pain due to cervical disc herniation (1 article), patients with chronic lumbar radicular pain due to disc protrusion or failed back surgery syndrome (FBSS) or patients with chronic lower extremity pain due to FBSS (4 articles), patients with intractable pain due to spinal stenosis, or patients with chronic radicular pain due to spinal stenosis (2 articles), patients with chronic low back pain and sciatica or lower extremity pain (3 articles), and patients with radiating pain due to herniated intervertebral disc (1 article) were included.

Percutaneous epidural neuroplasty performed on patients with chronic low back pain and lower extremity pain was evaluated based on a total of ten articles of literature, and the study results are as follows.

For safety, complications such as catheter rupture, placing the catheter in the epidural space, and subarachnoid entries were confirmed in 2 to 11.67% of the group that performed percutaneous epidural neuroplasty (hereinafter the

'intervention group'). In addition, swelling, redness, itching, and transient sensory deficit were reported in 6.5 to 91.3%.

Accordingly, there was the subcommittee's opinion that complications such as swelling, redness, itching, and transient sensory deficit were acceptable as temporary or resolvable complications. However, with respect to complications such as catheter rupture, placing the catheter in the epidural space, and subarachnoid entries, the currently selected literature was of the opinion that serious complications may occur if the drug is administered while the catheter is inserted into the spinal cavity. The procedure was performed after confirming the location of the catheter through epidurogram while administering a contrast agent. If the catheter entered a site other than the epidural space, the catheter was removed immediately and did not cause a dangerous situation, so it is judged that the related complications were simply mentioned in the literature. Since this procedure is a high-risk technique, there was the opinion that safety was acceptable if it was performed under considerable caution and supervision and appropriately dealt with in a dangerous situation.

As for effectiveness, the intervention group reported significantly improved effects on pain and function compared with conservative treatment, placebo group, and epidural nerve block. However, most of the selected literature had a high dropout rate or a high proportion of patients who were unblinded, and there was no clear explanation of the concurrent treatment between the intervention group and the comparative group or how the treatment effect was adjusted. In some studies, the level of evidence was evaluated as 'low' due to the high risk of bias because injections were administered more than once in the intervention group or because the number of injections was not clearly explained.

Accordingly, the subcommittee was of the opinion that although intervention procedures could consistently confirm more effective research results in reduction pain and improving function in patients with chronic low back pain and lower extremity pain, the level of evidence was low, so confidence in the evidence could be limited.

Percutaneous epidural neuroplasty in patients with cervical pain was evaluated based on one literature review comparing it with an epidural nerve block. As a result of safety, no complications were reported in both groups. As a result of effectiveness, the degree of pain improvement was reported to be significantly higher in the intervention group at 12 months of follow-up, and the degree of functional improvement was significantly higher in the intervention group at 6 months. However, no significant difference was reported between groups at 12 months.

Therefore, the subcommittee judged that it could not be evaluated because there was insufficient evidence to judge the safety and effectiveness of this technology since there was only one selected literature for cervical pain patients.

Conclusion

The percutaneous epidural neuroplasty subcommittee made the following suggestions based on the current assessment results.

When performing percutaneous epidural neuroplasty for patients with chronic low back pain and lower extremity pain, it is necessary to perform it under considerable caution and supervision, considering that this technique has a high risk of performing the procedure. Effectiveness was consistently significant in terms of pain reduction and functional improvement compared to conventional conservative treatment and epidural nerve block, so the opinion was that there was no problem in the clinical use of this health technology. However, considering that the level of evidence is limited, it was judged that it is necessary to continuously accumulate more evidence through well-designed studies to increase the strength of the recommendations. It is difficult to evaluate with only one selected literature because there is insufficient evidence to evaluate safety and effectiveness when it is performed on patients with cervical pain. For the assessment of this technique in the future, it was determined that it was necessary to accumulate more evidence through well-designed study results compared with techniques within the reimbursement coverage such as epidural nerve block.

Based on the review results of the subcommittee, the Health Technology Reassessment Committee deliberated on ‘percutaneous epidural neuroplasty’ for spinal pain patients including chronic back pain, lower extremity pain, and cervical spine pain as follows (2020.12.11.).

The safety of percutaneous epidural neuroplasty is acceptable when it is performed to reduce pain in patients with spinal pain. Compared with the existing conservative treatment and epidural nerve block, it was evaluated as an effective technique because it was able to confirm a consistently significant effect in reduction pain and improving function. However, considering the limitation of the low level of evidence, it was determined that it was necessary to continue to accumulate high-quality evidence compared to the appropriate comparative procedure used in the current reimbursement coverage. In addition, although the procedure was performed after confirming the catheter position in most of the selected literature, there was an opinion that it is necessary to be performed under considerable caution and supervision since serious complications may occur if the drug is administered while the catheter is inserted into the spinal cavity. In the case of patients with cervical pain, there was an opinion that a more careful approach is necessary considering the anatomical location and the difficulty of the procedure.

Therefore, the Health Technology Reassessment Committee deliberated that

percutaneous epidural neuroplasty for pain reduction in patients with spinal pain was recommended (Recommendation grade I-b).

Key Words

Spinal pain, Percutaneous epidural neuroplasty, Safety, Effectiveness