2020 Health Technology Reassessment Report

Percutaneous epidural neuroplasty with balloon catheter

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Summary

Background of Assessment

The percutaneous epidural neuroplasty with a balloon catheter is a technology performed to reduce pain in patients with spinal pain. It is a procedure in which a catheter for neuroplasty with percutaneous balloon dilatation function inserted into the epidural space to remove adhesions in lesions of the epidural space or expands the intervertebral foramen through dilation and relaxation of a balloon attached to the tip of the catheter 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 with balloon catheter were evaluated at the 2nd Health Technology Reassessment Committee (2020.2.14.) in 2020 after reviewing the assessment protocol and subcommittee composition plan.

Assessment Method

In this assessment, a systematic literature review was performed to evaluate whether percutaneous epidural neuroplasty with a balloon catheter 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. Two evaluators independently applied the literature inclusion and

exclusion criteria to perform literature selection. Data extraction, risk of bias assessment, and GRADE application were not performed with zero selected literature.

For this assessment, a subcommittee consisting of a total of 10 members (2 from the Department of Anesthesia 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 with a balloon catheter were finally reviewed.

Assessment Results

There were 0 articles selected for assessment of percutaneous epidural neuroplasty with a balloon catheter. In the case of comparative treatment, to evaluate the effect of interventional treatment, it was decided to consider the treatment used in the existing reimbursement coverages as appropriate treatment, and only studies compared with the comparative treatment were included in the selected literature for assessment. Therefore, before-and-after studies of percutaneous epidural neuroplasty with a balloon catheter or studies comparing the percutaneous epidural neuroplasty, which are currently not covered, were confirmed, but all were excluded as they were studies that did not compare with the pre-defined comparative procedure.

Accordingly, the subcommittee was of the opinion that in the case of percutaneous epidural neuroplasty with a balloon catheter, the safety and effectiveness of the technique could not be evaluated because no research has been confirmed that compares with the existing technology registered in the reimbursement coverage and there was not enough evidence to judge the safety and effectiveness of the technology.

Conclusion and Suggestions

The subcommittee for percutaneous epidural neuroplasty with balloon catheter made the following recommendations based on the current assessment results.

The percutaneous epidural neuroplasty with a balloon catheter is difficult to evaluate due to lack of evidence because there is no study comparing it with the technology currently within the reimbursement coverage. It was judged that it was necessary to accumulate more evidence through well-designed research results

compared with technologies within the reimbursement coverage such as epidural nerve block for the assessment of this technology in the future.

The Health Technology Reassessment Committee deliberated on ‘percutaneous epidural neuroplasty with a balloon’ as follows based on the review results of the subcommittee (2020.12.11.).

Although the safety of percutaneous epidural neuroplasty with a balloon catheter is acceptable when performed for pain reduction in patients with spinal pain, there have been no comparative studies with conventional conservative treatment and epidural nerve block. But, 6 articles reporting the effects before and after the procedure (2 comparative studies with percutaneous epidural neuroplasty, 1 study before and after the procedure, and 3 case reports) were confirmed. It was evaluated as an effective technology similar to percutaneous epidural neuroplasty since it uses a method similar to percutaneous epidural neuroplasty in the term of removal the adhesion of epidural lesions by percutaneously inserting a catheter although the type of catheter is different. It was suggested that the accumulation of high-quality evidence compared with the appropriate procedure currently used in the reimbursement coverage is necessary. In addition, there was an opinion that the technology needs to be performed under considerable caution and supervision in the same way as percutaneous epidural neuroplasty because it has similar safety to percutaneous epidural neuroplasty.

Therefore, the Health Technology Reassessment Committee deliberated that percutaneous epidural neuroplasty with a balloon catheter for pain reduction in patients with spinal pain was recommended (Recommendation grade I-b).

Key Words

Spinal pain, Percutaneous epidural neuroplasty with a balloon catheter, Safety, Effectiveness