2020 Health Technology Reassessment Report

Nucleoplasty

NECA
한국보건의료연구원

Summary

Background of Assessment

Nucleoplasty is a technology that reduces intra-discal pressure by inserting a radiofrequency probe into the disc and repeating ablation and coagulation through advancing and retracting to vaporize and remove disc materials.

In Korea, since 2005, it has been used including in the category of “Intradiscal Electrothermal Therapy (Article-83)”, which is a non-benefit item, as the name of the service in ‘intradiscal radiofrequency thermal coagulation’. This technology is included in the government's 「Plan for Benefit Expansion in Non-benefit Items 'Spine, Musculoskeletal System, and Pain' in 2020. Since the related item has a large non-reimbursement scale and it is expected that various issues will arise when changing benefits, the Ministry of Health and Welfare requested a re-assessment, and safety and effectiveness were evaluated to review the feasibility of benefit conversion.

The assessment protocol was deliberated by the 2nd Health Technology Reassessment Committee in 2020, and the subcommittee consisted of a total of 10 experts including 2 from the Department of Evidence-Based Medicine, 2 from the Department of Anesthesiology and Pain Medicine, 2 from the Department of Neurosurgery, 2 from the Department of Orthopedic Surgery, 1 from the Department of Rehabilitation Medicine, and 1 from Department of Radiology.

Assessment Method

To confirm the clinical safety and effectiveness of nucleoplasty in patients with discogenic pain, it was evaluated using a systematic literature review method. In the safety evaluation, it was limited to draw conclusions only from comparative studies, so single-arm studies were also included.

For the systematic literature review, three overseas and five domestic databases were searched based on key questions, and two reviewers independently screened and selected them according to the literature inclusion and exclusion criteria. The risk of bias evaluation in the literature was conducted independently by two reviewers using RoB and RoBANS, and a consensus was reached. Data extraction was performed independently by two reviewers using a pre-determined data extraction format, and in case of disagreement, it was discussed with a third party and an agreement was reached.

A qualitative review was performed for data analysis. As a result of the systematic

literature review, the level of evidence was evaluated according to the Grading of Recommendations Assessment Development and Evaluation (GRADE) method.

Assessment Results

A total of 75 pieces of literature were selected for the evaluation of nucleoplasty, and 49 articles for the lumbar vertebrae and 26 articles for the cervical vertebrae were classified by area to be applied. For the lumbar region, there were 13 comparative studies (6 randomized comparative studies, 7 non-randomized comparative studies) (1,539 subjects in total) and 36 single-arm studies (3,589 subjects in total) by study type. For the cervical spine, there were 7 comparative studies (4 randomized comparative studies, 3 non-randomized comparative studies) (650 subjects in total) and 19 single-arm studies (1,330 subjects in total) by study type.

The evaluation results of nucleoplasty were presented separately for each lumbar and cervical spine region, according to the comparative treatment group (surgical treatment, minimally invasive treatment, and conservative treatment) for safety and effectiveness.

Lumbar spine

The safety of nucleoplasty was evaluated based on a total of 45 pieces of literature (9 comparative studies, 36 single-arm studies).

In the case of comparative studies, 1.3-3.8% of complications were reported only in the comparison group in one study compared to surgical treatment (3 articles). In a study compared with minimally invasive treatment (5 articles), complications were reported in 0-11.5% for the intervention group and 0-17.5% for the control group. In the study compared with conservative treatment (1 article), no clinical side effects and complications were reported in the intervention group.

In single-arm studies, 22 studies (64.7%) reported no complications related to nucleoplasty, and 14 other studies reported side effects and complications.

Among the complications, the subcommittee considered discitis, neurological damage, cerebrospinal fluid leakage, and hematoma as major complications that need to be considered clinically meaningfully. Discitis (5 articles) was reported 0.25% (1/396) - 10% (5/50), neurological adverse reactions (6 articles) was 0.5 (2/396) - 20.4% (10/49), cerebrospinal fluid leakage (1 article) was 9.6% (5/52), and hematoma (1 article) was reported in 5.8% (3/52). As for other minor complications, needle puncture site pain (5 articles) was reported in 6.4-75.5% of cases, and all of these cases were temporary and resolved within 2 weeks and 4

weeks after the procedure. It was also reported that needle puncture site-related bleeding occurred in 2 articles and needle puncture site-related infection occurred in 1 article. Epidural fibrosis was also reported in 1 article (1 case).

The effectiveness of nucleoplasty was evaluated based on a total of 13 pieces of literature.

In a study comparing surgical treatment (3 articles), it was confirmed that the degree of pain and functional improvement improved before and after the procedure in both treatment groups. When comparing the two treatment groups, it was confirmed that the comparison group was better in only one article for the statistically significant effect differences.

In a study compared with minimally invasive treatment (8 articles), it was confirmed that the degree of pain and functional improvement improved before and after the procedure in both treatment groups.

In 5 studies comparing the two treatment groups, the intervention group showed better pain and function improvement. In the 3 studies, the improvement effect was better in the control group. Quality of life and patient satisfaction were significantly better in the intervention group.

In a study compared with conservative treatment (2 articles), It was confirmed that pain and functional improvement were better in the intervention group.

Cervical spine

The safety of nucleoplasty was evaluated based on a total of 26 pieces of literature (7 comparative studies, 19 single-arm studies).

In the comparative study, no complications were reported in both treatment groups in the study comparing surgical treatment (1 article), and 0-17.6% of the intervention group and 1.0-17.6% of the control group in the study compared with minimally invasive treatment (3 articles). In a study comparing conservative treatment (3 articles), it was reported that there were no complications in the intervention group.

In single-arm studies, it was reported that no complications related to nucleoplasty occurred in 4 studies (33.3%), and cases such as pain, disc herniation, device related problems, and hematomas were reported in 11 studies.

Among the complications, the subcommittee considered discitis, device-related problems (eg, broken device), and hematomas as complications that need to be considered clinically meaningfully. Discitis was reported in 4 articles, 1 case each. As for device-related problems, 2 articles reported each one case (0.79, 2.2%) in which the electrode tip/spinewand was broken and remained in the intervertebral

disc space, and the patient's condition was reported to have maintained good clinical results without complications. The subcommittee reported that the patient's condition maintained good clinical results without any additional complications, so it did not lead to a major safety problem. However, it is suggested that attention should be paid to safety during the procedure, as the procedure itself may cause the tip to break easily during the procedure, and the risk of serious secondary complications due to tip breakage cannot be ruled out. The anterior hematoma was reported in 2 articles in each of 1 case.

Other minor complications, such as pain that are temporary or resolved within a few days, were reported in 0.74-46.4% (3 articles), Horner's syndrome such as anterior cervical pain and hoarseness in 0.39-10.4% (2 articles), and ecchymosis at the needle insertion site in 10.7% (1 article).

The effectiveness of nucleoplasty was evaluated based on a total of 13 pieces of literature.

In a study comparing surgical treatment (1 article), it was confirmed that the degree of pain and functional improvement was significantly improved before and after the treatment in both treatment groups, but there was no difference in effect between the two groups.

In the study (3 articles) compared with minimally invasive treatment, the index score of both treatment groups improved after treatment, but there was no significant difference between the two treatment groups. There was no significant difference in patient satisfaction (1 article).

In a study compared with conservative treatment (3 articles), it was reported that there was a significant improvement in pain and functional improvement in the intervention group. The quality of physical life (1 article) was found to be significantly improved in the intervention group compared to the control group.

Conclusion and Suggestions

Based on the current literature, the subcommittee presented the safety and effectiveness results of nucleoplasty for patients with lumbar and cervical discogenic pain as follows.

In a safety-related lumbar and cervical spine comparative study of nucleoplasty, no complications or some reported cases were confirmed at a low or similar level. In single-arm studies, various complications were reported on lumbar vertebrae in 12 articles (35.2%) and on cervical vertebrae in 8 articles (66.7%). In the literature, all cases have been reported as transient or resolved. However, it was the opinion that the case of discitis, neurological adverse events, cerebrospinal fluid leakage, and hematoma reported in some lumbar spine studies and cases

of discitis, device-related problems, and hematomas reported in cervical spine studies, were clinically meaningful than caution and needed to be considered.

Efficacy-related nucleoplasty in the lumbar spine showed less pain reduction and functional improvement compared to surgical treatment. However, a significant effect was confirmed compared to conservative treatment, and similar or significant effects were confirmed as other minimally invasive treatments. Nucleoplasty in the cervical spine showed significant effects on pain reduction and functional improvement compared with conservative treatment, but there was no significant difference in effect between surgical treatment and minimally invasive treatment.

Therefore, the subcommittee had the following opinions on the safety and efficacy of nucleoplasty. As a procedure to treat patients with lumbar and cervical discogenic pain, serious complications were reported in a single-arm study, but they resolved without sequelae. It did not cause complications or is safe at a similar level compared to other treatments. It is a technology that is more effective than conservative treatment and is effective at a level similar to other minimally invasive.

The Health Technology Reassessment Committee deliberated on “nucleoplasty” as follows based on the subcommittee’s review results (2020.12.11.).

Nucleoplasty is a health technology for treating patients with discogenic pain, and it has been shown to have no complications or a similar level of safety compared to other treatments. However, some major complications have been reported in single-arm studies, so attention is needed. In addition, in terms of pain and functional improvement, it was evaluated as an effective technique because it was more effective than conservative treatment and it was found to have a similar level or significant effect to other minimally invasive treatments. Therefore, the Health Technology Reassessment Committee deliberated nucleoplasty as a 'recommended' (recommendation grade I-b) as a health technology for treating pain in patients with discogenic pain.

Keywords

Discogenic pain, Disc herniation, Low back pain, Radicular pain, Nucleoplasty, Percutaneous disc decompression