



Summary

Background of Assessment

Intradiscal Electrothermal Therapy (IDET) is a health technology that has been registered as a non-benefit item since 2005 in Korea and has been used until now. It is the practice of relieving pain by giving high-temperature heat damage to the nerve tissue that has grown into the damaged annulus fibrosus. Health technology reassessment was performed at the request of the Ministry of Health and Welfare as this technology has a large non-reimbursement scale and it is expected that various issues will arise during the conversion of benefits.

The evaluation plan was deliberated at the 2nd health technology reassessment committee (2020.02.14.) in 2020, and the safety and effectiveness evaluation results were finally reviewed at the 2020 12th health technology reassessment committee (2020.12.11.).

Assessment Method

Safety and effectiveness evaluation of IDET was conducted through a systematic literature review. All evaluation methods were finalized after deliberation by the "Intradiscal Electrothermal Therapy Subcommittee (hereinafter referred to as the subcommittee)" in consideration of the research purpose. The key question of the assessment was "What is the clinical safety and effectiveness of Intradiscal Electrothermal Therapy (IDET) in patients with discogenic pain?". Safety was evaluated for side effects and complications in comparative studies and single-arm studies, and effectiveness was evaluated by indicators such as pain score, functional evaluation, and quality of life in comparative studies.

A literature search was conducted in 3 overseas databases and 5 domestic databases, and two reviewers independently screened and selected them according to the literature inclusion and exclusion criteria. According to the study type, the risk of bias assessment in the literature was conducted independently using Cochrane's Risk of Bias and ROBANS ver. 2.0 by two reviewers to reach a consensus of opinion. Data extraction was performed independently by two reviewers using a pre-determined data extraction format, and in case of disagreement, it was agreed upon by discussion with a third party. Data analysis was performed according to the type of control method. If the quantitative analysis was possible, meta-analysis was performed, and if a quantitative analysis was not possible, a qualitative review was performed. For the results of the systematic literature review, the level of evidence was evaluated using the GRADE method.

Assessment Results

As a result of the systematic literature review, a total of 56 studies (62 articles) related to Intradiscal Electrothermal Therapy (IDET) were selected. All studies were conducted on low back pain (back pain), and the research published in early 2000 was the largest with 53.2%. 10 comparative studies (13 articles) and 46 single-arm studies (49 articles) were included.

Safety

In 54 studies (8 comparative studies, 46 single-arm studies), the clinical safety results of Intradiscal Electrothermal Therapy (IDET) were confirmed.

In one non-randomized comparative study comparing IDET and surgical treatment, neither group showed no infection or complications. In one non-randomized comparative study comparing IDET and minimally invasive treatment, it did not mention complications in IDET. Of the six studies comparing IDET with conservative treatment, three studies reported no side effects or complications in both groups, but in two studies, side effects and transient neuromyopathy occurred in 11 to 12% of patients after IDET. Of the 46 single-arm studies performed on patients who underwent IDET, 22 (47.8%) studies reported no complications after IDET. In 24 studies (52.2%), various side effects and complications were reported within the range of 1.3 to 29.4%. From mild symptoms, serious complications such as discitis, osteonecrosis, Cauda equina syndrome, and complex regional pain syndrome were also identified.

Effectiveness

In 10 comparative studies, the clinical effectiveness of Intradiscal Electrothermal Therapy (IDET) was confirmed.

In two non-randomized comparative studies comparing IDET and surgical treatment, there was no significant difference between the two groups in terms of pain improvement, functional improvement, and quality of life. However, in one non-randomized comparative study compared with minimally invasive treatment, pain score reduction was better with the other minimally invasive treatment (intradiscal injection), and the duration of pain recurrence was significantly better with IDET. Seven studies comparing IDET with conservative treatment showed that IDET was significantly better than conservative treatment in terms of pain improvement, functional improvement, and quality of life. Other than that, there was no significant difference between the two groups in the depression scale,

treatment success, and body awareness rating.

Conclusion and Suggestions

The Intradiscal Electrothermal Therapy (IDET) subcommittee made the following recommendations based on the current evaluation results.

IDET was found to have no complications or a similar level of safety compared to other treatments. However, caution is needed since some serious complications such as osteonecrosis, discitis, cauda equina syndrome, and complex regional pain syndrome have been reported. In terms of effectiveness, IDET was not significantly different from surgical treatment, but it was found to be significantly better in some outcome indicators compared to other minimally invasive treatments and more effective than conservative treatment.

Accordingly, the health technology reassessment committee deliberated as follows based on the subcommittee review results (2020.12.11.). "Intradiscal Electrothermal Therapy (IDET)" as a medical technology to treat pain in patients with discogenic pain was reviewed as 'recommended' (recommendation grade I-b), and the reasons for the recommendation are as follows. IDET has been shown to have no complications or a similar level of safety compared to other treatments, but caution is needed as some major complications have been reported in single-arm studies. Although there was not enough evidence to compare effectiveness with surgical treatment and other minimally invasive treatments currently used in clinical practice, it was judged as an effective health technology rather than conservative treatment.

Keywords

Low Back Pain, Intradiscal Electrothermal Therapy (IDET), Minimally Invasive Spine Surgery (MISS), Safety, Effectiveness