

Intradiscal electrothermal therapy (IDET) for low back pain

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Summary

- *Intradiscal electrothermal therapy (IDET) is a minimally invasive surgical procedure for the treatment of chronic low back pain in patients with intact or slightly degenerated discs that are presumed to be responsible for the pain.*
- *Among the adult population, approx. 35% have had transient or chronic low back pain within the past year. Approx. 3.5% of all adults are seriously affected by low back pain.*
- *The indications for treatment with IDET are far from having been clarified as yet.*
- *So far there has only been a single randomised controlled clinical trial of IDET, although there are numerous clinical outcome studies and reviews of data on patients who have undergone this treatment. The literature does not yet provide a clear picture of IDET's clinical effect, though.*
- *As there is no convincing documentation for the indications and treatment results, in the event that IDET is introduced in Denmark this should take place via a randomised controlled clinical trial.*

The disease

Low back pain is an extremely common condition in Denmark. Among the adult population, approx. 35% have had transient or chronic low back pain in the past year [1]. Chronic pain is understood to mean persistent pain that has lasted for more than 7 weeks [2]. Approx. 3.5% of all adults are severely affected by low back pain at any one time [3].

The pain can be attributable to various conditions in and around the spinal column, including various types of damage to the intervertebral discs, e.g. herniation, disruption (fissures), prolapse and degeneration.

The differentiation of discogenic pain, which is seen with disc disruption without actual root compression, is difficult. Moreover, the condition is poorly defined as the pain can stem from other adjacent structures, for example the facet joints, muscle tissue or degenerated discs with associated bone inflammation.

The causes of the discogenic pain seen with disc disruption are complex and far from fully understood [4]. Some patients with chronic low back pain have neither disc protrusion, prolapse nor degeneration. One of the hypotheses is that chronic low back pain is primarily discogenic and derives from cracks that extend from within the disc nucleus (nucleus pulposus) to the outer part of the disc (annulus fibrosus), though without penetrating it [5;6]. In the outer 1/3 of the annulus fibrosus there are nerve fibres that can possibly be stimulated, thereby generating the pain. Moreover, fine nerve endings

can grow deeper into the disc via the cracks and cause pain upon movement or strain upon the spinal column [2;6].

The great problem is to localise the structure in the back causing the pain. Degenerated discs only infrequently cause pain and, as mentioned above, the pain could be generated from many possible locations, both inside and outside the vertebral column.

Current treatment

Patients with chronic low back pain are usually initially offered conservative treatment [1;7]. This predominantly consists of painkillers, manual treatment (physiotherapy, massage, chiropractic, etc.), exercise therapy and back schools.

If the pain is permanent and disabling despite this treatment, a radiological examination will normally be carried out using conventional radiography, CT scanning and/or MR imaging.

At present, no invasive treatment is available in Denmark that is routinely initiated if conservative treatment of discogenic pain proves ineffective. (A new invasive treatment form for this patient group – the discus prosthesis – should be mentioned, but is not otherwise considered in this Health Technology Alert).

New treatment

Intradiscal electrothermal therapy (IDET) is a minimally invasive surgical procedure for the treatment of intact or slightly degenerated painful discs. The indications for the procedure have not yet been clarified. According to the literature, IDET has been offered to patients with chronic low back pain who are unresponsive to conservative treatment of at least six months duration.

The disc may only be slightly degenerated without any sign of nerve root compression, i.e. without causing pain upon lifting of a stretched leg, or other signs of nerve root compression. Prior to the procedure, discography of the affected disc is performed to provoke the pain [5;8]. Pain-provoking discography is rarely used in Denmark to identify painful discs. This is because the diagnostic value of the method is open to discussion [9–11].

With IDET, the fissured part of the disc is heated in a controlled manner under local anaesthesia. Under fluoroscopic guidance a flexible hook-shaped catheter containing a heating coil is inserted in the outer edge of the annulus fibrosus, whereafter it is heated electrically to approx. 90°C for approx. 17 minutes. The hypothesis is that the heating is completely local and should cause coagulation of the collagen tissue and destruction of the nerve endings [4;5], thereby reducing the pain. There is some uncertainty about this hypotheses, however, as mentioned below in the section on evidence [12;13].

At present there are at least three percutaneous systems for electrocoagulation and/or decompression of discs: Radionics RF Disc Catheter System® from Radionics, ArthroCare System 2000® from ArthroCare and SpineCATH® from Smith & Nephew [14;15]. The first two employ a straight catheter and are used to coagulate the nucleus of the disc (nucleoplasty). Other methods for heating discs also exist, for example ultrasound or short-wave radiation.

This Health Technology Alert solely concerns the most widespread system, SpineCATH®, for coagulation of the annulus fibrosus (annuloplasty).

The intervention can be performed on an out-patient basis, but is followed by a 6 to 8-week period of mild rehabilitation and restriction of physical strains such as sitting activities, work and motoring, among other means through the use of a back support. Greater strains must be avoided for approximately six months [16].

Use in Denmark

IDET is not yet in use in Denmark. SpineCATH® and the associated equipment bear the CE-mark, though, and can thus be marketed throughout Europe. SpineCATH® will most likely be marketed in Denmark within the immediate future [17].

Evidence

There are a number of clinical studies of IDET, but as yet only a single randomised, double-blind placebo-controlled trial, and this only encompasses a relatively small and highly selected population [18]. The study revealed a statistically significant physical and mental improvement in the intervention group of 32 patients at the six months follow-up relative

to the placebo group of 23 patients who underwent the same procedure except for the electrocoagulation step.

The current combined documentation pertaining to IDET thus suffers from a lack of randomisation and the use of biased control groups [7]. Furthermore, no articles have been published with follow-ups exceeding two years and much of the documentation can be directly related to the inventors of the technology or to the manufacturer of SpineCATH® [19–22].

There is no convincing documentation as to the treatment's presumed mechanism of action, i.e. coagulation of the collagen and destruction of the nerve endings [5;23]. Animal and cadaveric experiments suggest that this hypothesis is not valid, however, because the number of nerve fibres found after six weeks is the same both with and without IDET treatment and, with the exception of a very restricted area around the catheter, the temperature measured is not sufficiently high to cause coagulation of the collagen tissue [12;13]. More studies are needed concerning the mechanism of action [24].

Several studies have examined data on patients who have undergone IDET treatment, both clinical outcome studies and reviews [4;7;16;25]. There is no clear agreement about the real effect of IDET treatment, however.

The treatment seems to be relatively safe since no serious side effects have been reported from the clinical trials [5], and only a few case stories have been published reporting severe complications such as osteonecrosis [26] and compression of the distal part of the spinal nerves (cauda equina syndrome) [27;28].

If the treatment effect recorded in these studies is viewed in an overall perspective, the results indicate that the patients experience improvement following IDET in the form of pain alleviation and a greater tolerance for standing and sitting activities. There is uncertainty about the long-term effect of the treatment, though, as some studies indicate a continued effect at follow-up two years after the intervention [19;25], while others indicate a declining effect after two years and deterioration in up to 20% of the patients [29]. Thus no certain long-term results are available, just as the long-term effect of thermal treatment of discs is unknown.

Ongoing trials

A large number of clinical trials are currently underway in the USA. So far these have only been presented in the form of conference abstracts [14]. A common feature of several of these studies, however, is that they lack randomised control groups.

Costs

The cost of the equipment needed to perform one single IDET procedure is approx. DKK 6,000 (excluding VAT). Moreover, a special generator is needed that costs approx. DKK 90,000 [30]. In addition there is the cost of the preceding discography. The intervention has to be done under fluoroscopic control. The IDET procedure can be carried out on an out-patient basis.

Implementation

This treatment represents a new possibility for a patient group with severe symptoms for which no real alternative treatment is usually available at present. Hence, a great demand for this new treatment can be expected. It is important to define the indications for which it will actually be possible to achieve results with this treatment, however. The majority of these patients will not be candidates for other surgery, but compared with conventional back surgery, treatment with IDET is considerably less invasive and can be performed on an out-patient basis under local anaesthesia [7].

In the literature it is recommended that the procedure be preceded by discography, which is not currently a standard procedure in Denmark, but the question of the value of discography as a diagnostic tool in the identification of discogenic pain is controversial, however.

The distributor states that the equipment needed for IDET will be sold exclusively to doctors/hospitals that have undergone introductory and proficiency courses in the use of IDET [30], but it presumably only requires a one-day course to learn to perform the IDET procedure [31]. In view of the sparse literature on controlled clinical trials of IDET and the somewhat uncertain indications for offering the procedure, any introduction of IDET in Denmark should be on a trial basis via a national, randomised, controlled clinical trial.

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