Intradiscal Electrothermal Therapy (IDET) for the Treatment of Chronic, Discogenic Low Back Pain

Before CCOHTA decides to undertake a health technology assessment, a pre-assessment of the literature is performed. Pre-assessments are based on a limited literature search; they are not extensive, systematic reviews of the literature. They are provided here as a quick guide to important, current assessment information on this topic. Readers are cautioned that the pre-assessments have not been externally peer reviewed.

Introduction

Low back pain is a common medical condition. Most back pain resolves spontaneously, but chronic low back pain may be due to deterioration of vertebral discs. These discs have a soft centre (the nucleus pulposis) and a harder, fibrous exterior wall (the annulus fibrosis). Discs act as cushions between the vertebrae of the spine.\(^1,2\) If a disc is damaged, either due to injury or the wear and tear associated with aging, the soft interior nucleus may bulge into the wall, deforming the shape of the disc and causing back pain.

For the initial treatment of low back pain, conservative therapies are used. These may include massage, physiotherapy, spinal manipulation, exercises to strengthen the back, and anti-inflammatory drugs, including corticosteroid medications. Surgical interventions may be considered if the pain persists. Surgery can involve the removal of the damaged disc using various methods, the insertion of a prosthetic disc, or spinal fusion, which fuses the bones on each side of the damaged disc to relieve stress on the area.

Several less invasive procedures have also been introduced for the treatment of damaged discs. One alternative is intradiscal electrothermal therapy (IDET).\(^3\) The proprietary name for the technology used in IDET is the SpineCATH® IntraDiscal ElectroThermal™ therapy using the Electrothermal Spine System developed by ORATEC Interventions Inc. (now Smith & Nephew, Inc., Endoscopy Division).\(^3\) The SpineCATH system received a 510(k) approval from the US Food and Drug Administration (FDA) in 1998. It has also been licensed by Health Canada.\(^4,5\) The FDA approval specified the following indications: “The SpineCATH Intradiscal Catheter is intended for use for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.”\(^4\) Subsequent FDA Warning Letters advised the manufacturer that the device must not be marketed as a treatment for the broad indication of lower back pain, as it is approved only for the treatment of lower back pain associated with the specific indication of annular disruption of contained herniated discs.\(^5\)

In IDET a thermal coil, inserted via a catheter under fluoroscopic guidance, is used to heat the annulus fibrosis of the damaged disc. The heat is believed to modify the collagen of the disc wall, causing it to contract and thicken. This may reduce disc deformation. The heat may also destroy pain receptors within the wall of the disc. The treatment is performed under local anesthetic, with mild sedation, as an out-patient, procedure. The patient is advised to wear a back brace for about six weeks post-procedure, and an exercise or physiotherapy program may also be recommended. Most of the literature evaluating this

\(^{a}\) Also referred to as intradiscal electrothermal catheterization, intradiscal electrothermal anuloplasty/ annuloplasty, electrothermal arthroscopy, thermodiscoannuloplasty, or intradiscal electrothermal coagulation.
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The main question regarding IDET is whether this treatment offers an effective alternative to existing treatments. The main problem is that the available evidence is of poor quality \(^7\),\(^12\),\(^13\) (as is the case for many of the therapies used in the treatment of back pain). However, as a recent coverage policy from a US health insurer explains:

> The alternative to IDET for some patients is spine fusion. The results of the various IDET published clinical series report low morbidity and low adverse outcomes compared to spine fusion. In addition, the data documenting the overall effectiveness of IDET with the Oratec SpineCATH in reducing back pain and improving quality of life appears to be as good or better than that of fusion…\(^{14}\)

The long-term safety and effectiveness of IDET, and whether patients will require re-treatment to maintain pain relief, is not yet known.\(^{15}\)

Assessment Process

Preliminary literature searches of PubMed, The Cochrane Library (issue 1, 2003) and the CRD databases (HTA, DARE and NHS EED) databases were performed in March 2003. In addition, the web sites of individual HTA agencies were scanned. An internet search of Google.com provided further background references, and ongoing trials were identified through Clinicaltrials.gov and the UK National Research Register. Helene Ørsted, at the Danish Centre for Evaluation and Health Technology Assessment (DACEHTA), kindly provided additional references from the literature search conducted for the DACEHTA assessment of this technology. The publications summarized in the table below are health technology assessments or systematic reviews published since 1998 or currently in progress.
## Summary of Findings

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<th>Type of Report</th>
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<tr>
<td>HTA</td>
<td><strong>Intradiscal electrothermal anuloplasty</strong>: a treatment for patients with chronic low back pain due to anular disruption of contained herniated discs. Canberra: Medical Services Advisory Committee; 2002. Available: <a href="http://www.msac.gov.au/pdfs/msac1048.pdf">http://www.msac.gov.au/pdfs/msac1048.pdf</a></td>
<td>“Since there is currently insufficient evidence pertaining to intradiscal electrothermal anuloplasty, a treatment for patients with chronic low back pain due to anular disruption of contained herniated discs, MSAC recommended that public funding should not be supported at this time for this procedure.”</td>
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“An Australian trial is being planned; A Prospective Clinical Outcome Study to Evaluate the Use of Intradiscal Electrothermal Annuloplasty (IDETA) with The SpineCATH™ Followed By A Standardised Physical Therapy Program for Chronic Discogenic Low Back Pain. The primary objectives of this trial are to study pre- and postoperative outcomes at 3, 6, 12, 24 and 60 months after IDET. Pain, function, health care utilisation and cost effectiveness will be studied.” |

A consumer summary is also available at: [http://www.bcbs.com/consumertec/ctect_17_11.html#7](http://www.bcbs.com/consumertec/ctect_17_11.html#7)
| HTA | Intradiscal electrothermal therapy (IDET) for low back pain [TA #062]. Bloomington (MN): Institute for Clinical Systems Improvement; 2002. Available: http://www.icsi.org/knowledge/detail.asp?catID=107&itemID=557 | - “There is no convincing evidence that shows the short or long-term clinical efficacy of this procedure. Only subjective outcomes from case series and one non-randomized trial have been reported. Blinded, randomized studies comparing the procedure to a placebo treatment or alternative treatments such as spinal fusion have not been done and are needed to develop any conclusion about efficacy of the procedure…”
- “The procedure is acceptably safe when performed by a physician trained in IDET, experienced in the diagnosis and management of low back pain, and experienced in the placement of needles into the intravertebral disk. Short term studies have indicated few adverse effects of IDET, but information on long-term effects is limited.”
- “The long-term effects of thermal coagulation of the disk are unknown at this time.” |
- “IDET represents a new minimally invasive alternative to other surgical techniques for persistent low back pain…IDET may be a preferable option for patients or whom conservative treatment has failed, with reduced hospital stay & operative times compared to other surgical techniques…”
- “Total annual treatment costs for the estimated maximum patient group [in the UK], 3,500, would be approximately £4.7M (£4 M for catheters and needles + £700,000 for generator hire). Compared to physical therapy IDET obviously represents a cost to the NHS, but this alternative does need to be balanced against the economic burden of chronic low back pain.” |
| HTA | Intradiscal electrothermal therapy (IDET) for lower back pain [Issue brief]. St. Paul (MN): Minnesota Health Technology Advisory Committee; 2001. Available: http://www.health.state.mn.us/h tac/idet.htm | - “While the initial data are promising, large randomized controlled trials are needed to determine safety, cost, effectiveness, and long-term outcome. Published research is limited and unrefined due to small sample size, poor study design, and lack of long-term data. Studies comparing IDET with other standard medical and surgical treatments are needed. Pain relief, which varies, is experienced by some patients, but not all. Pain may return due to new or preexisting disc damage.” |
Conclusion
Effective, minimally invasive treatments for chronic low back pain could reduce the substantial disability and costs of illness associated with this condition. Several agencies have recently published assessments of IDET. Although their conclusions have differed somewhat, all have agreed that the available evidence on this therapy is limited, and that long-term data on effectiveness and safety are lacking. The forthcoming Danish assessment on this treatment will provide a further analysis of the available evidence on this technology. In addition, several trials of this treatment that are currently underway should provide more conclusive evidence in future.2,16,17

References


