Intradiscal electrothermal therapy for discogenic low back pain
Intradiscal Electrothermal Therapy for Discogenic Low Back Pain

Technical brief prepared for AETMIS
by Reiner Banken

November 2005
This report was translated from an official French publication of the Agence d’évaluation des technologies et des modes d’intervention en santé (AETMIS). Both the original report, titled Le traitement des lombalgies d’origine discale par thermoplastie annulaire and the English report are available in PDF format on the Agency’s Web site.

Scientific review
Dr. Véronique Déry, MD, MSc, Chief Executive Officer and Scientific Director
Jean-Marie Lance, MSc, Senior Scientific Advisor

Translation
Mark Wickens, PhD, Certified Translator

Proofreading
Frédérique Stephan

Page layout
Frédérique Stephan

Bibliographic research
Denis Santerre

Coordination
Lise-Ann Davignon

Communications and dissemination
Richard Lavoie

For further information about this publication or any other AETMIS activity, please contact:

Agence d’évaluation des technologies et des modes d’intervention en santé
2021, Union Avenue, Suite 1050
Montréal (Québec) H3A 2S9

Telephone: (514) 873-2563
Fax: 514-873-1369
E.mail: aetmis@aetmis.gouv.qc.ca
www.aetmis.gouv.qc.ca

How to cite this document:

Legal deposit
Bibliothèque nationale du Québec, 2005
National Library of Canada, 2005

© Gouvernement du Québec, 2005.

This report may be reproduced in whole or in part provided that the source is cited.
MISSION

The mission of the Agence d’évaluation des technologies et des modes d’intervention en santé (AETMIS) is to contribute to improving the Québec health-care system and to participate in the implementation of the Québec government’s scientific policy. To accomplish this, the Agency advises and supports the Minister of Health and Social Services as well as the decision-makers in the health care system, in matters concerning the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including technical aids for disabled persons, as well as the modes of providing and organizing services. The assessments take into account many factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic implications.

EXECUTIVE

Dr. Luc Deschênes
Cancer Surgeon, President and Chief Executive Officer of AETMIS, Montréal, and Chairman, Conseil médical du Québec, Québec

Dr. Reiner Banken
Physician, Deputy Chief Executive Officer, Development and Partnerships

Dr. Véronique Déry
Public Health Physician, Chief Executive Officer and Scientific Director

Dr. Alicia Framarin
Physician, Deputy Scientific Director

Jean-Marie R. Lance
Economist, Senior Scientific Advisor

BOARD OF DIRECTORS

Dr. Jeffrey Barkun
Associate Professor, Department of Surgery, Faculty of Medicine, McGill University, and Surgeon, Royal Victoria Hospital (MUHC), Montréal

Dr. Marie-Dominique Beaulieu
Family Physician, Holder of the Dr. Sadok Besrour Chair in Family Medicine, CHUM, and Researcher, Unité de recherche évaluative, Hôpital Notre-Dame (CHUM), Montréal

Dr. Suzanne Claveau
Specialist in microbiology and infectious diseases, Hôtel-Dieu de Québec (CHUQ), Québec

Dr. Reiner Banken
Physician, Deputy Chief Executive Officer, Development and Partnerships

Dr. Alicia Framarin
Physician, Deputy Scientific Director

Jean-Marie R. Lance
Economist, Senior Scientific Advisor

Louise Montreuil
Assistant Executive Director, Direction générale de la coordination ministérielle des relations avec le réseau, ministère de la Santé et des Services sociaux, Québec

Dr. Jean-Marie Moutquin
Obstetrician/Gynecologist, Research Director, and Executive Director, Département d’obstétrique-gynécologie, CHUS, Sherbrooke

Dr. Réginald Nadeau
Cardiologist, Hôpital du Sacré-Cœur, Montréal, Board Member of the Conseil du médicament du Québec

Guy Rocher
Sociologist, Professor, Département de sociologie, and Researcher, Centre de recherche en droit public, Université de Montréal, Montréal

Lee Soderström
Economist, Professor, Department of Economics, McGill University, Montréal
FOREWORD

INTRADISCAL ELECTROTHERMAL THERAPY
FOR DISCOGENIC LOW BACK PAIN

Chronic low back pain constitutes a heavy burden for patients, their families and society, and it has major economic repercussions. The number of therapeutic approaches is increasing, but they are not always supported by evidence on their efficacy and safety. The Régie de l’assurance maladie du Québec (RAMQ) thus wanted to know about the present status of intradiscal electrothermal therapy.

Presently, a surgical approach—spinal fusion—seems to be the only generally accepted therapeutic option for chronic low back pain after failure of intensive multidisciplinary therapy. Its efficacy is, however, uncertain. Intradiscal electrothermal therapy, which is performed on an outpatient basis, could constitute a much less invasive alternative than spinal fusion if it proves to be effective and safe.

Over the past few years, several systematic health technology assessments have examined the efficacy and safety of intradiscal electrothermal therapy, including two briefs published in 2004. This assessment confirms the previous ones, according to which the efficacy evidence for this technology is limited. As for its safety, all the assessments conducted thus far consider this modality to be acceptably safe.

Given the seriousness of the disease and the lack of other proven treatments, the decision to no longer consider intradiscal electrothermal therapy an experimental technology can be considered reasonable. It is thus considered as an innovation that could sustain the quality of care, but its methods of application and its indications need to be further specified.

Consequently, the decision to include this technology as an insured service under the public plan should be conditional on its use by appropriately trained physicians in medical settings where continuous evaluation and research are conducted and on the creation of clinical registries for evaluating its effectiveness in Québec.

In submitting this report, AETMIS wishes to help improve, through an evidence-based medicine approach, the quality of the treatment of chronic low back pain in Québec.

Dr. Luc Deschênes
President and Chief Executive Officer
ACKNOWLEDGEMENTS

This report was prepared by **Dr. Reiner Banken**, MSc (Community Health), Consultant Researcher, at the request of the *Agence d’évaluation des technologies et des modes d’intervention en santé* (AETMIS).

The Agency would like to thank **Dr. Nathalie J. Bureau**, Radiologist, *Centre hospitalier universitaire de Montréal* (CHUM), and **Dr. Luc Marcoux**, Orthopaedic Surgeon, *Direction des services médicaux, Commission de la santé et de la sécurité du travail*, for their contribution in providing relevant and useful information.

The Agency would also like to thank the external reviewers, who have provided extremely helpful comments:

**Dr. Marc Filiatrault**
Physiatrist, *Hôpital Notre-Dame* (CHUM), and *Institut de physiatrie du Québec*, Montréal

**Dr. Charles Gravel**
Orthopaedic Surgeon, Chairman, *Comité sur l’exercice professionnel et les normes de pratique*, Quebec Orthopaedic Association, Montréal

**Dr. Michel Rossignol**
Medical Examiner, *Unité Santé au travail et environnementale, Direction de santé publique de Montréal*, Montréal

CONFLICT OF INTEREST

None declared.
INTRODUCTION

This brief was prepared at the request of the Régie de l'assurance maladie du Québec (RAMQ), which wanted to know if intradiscal electrothermal therapy for the treatment of chronic low back pain "should still be considered experimental and, if so, what the prospects are of it becoming medically recognized". The purpose of this assessment is therefore to determine if the currently available efficacy and safety evidence for intradiscal electrothermal therapy is sufficient for this treatment modality to no longer be considered as experimental.

LOW BACK PAIN

Most low back pain is of short duration. However, chronic back pain (persisting for more than three months) poses a considerable diagnostic and therapeutic challenge. Intensive multidisciplinary therapy should be systematically proposed to all patients, and it is only when such therapy fails that more extensive efforts should be made to establish a specific diagnosis.

Discogenic low back pain is a clinical entity characterized by pain that arises directly from one or more intervertebral discs, with no nerve root compression. The outline of the disc remains intact, but the disc is characterized by internal disruption due to radial annular tears. The diagnosis of discogenic low back pain is based on provocative discography. In this test, contrast material is injected, under low pressure, into a disc for the purpose of visualizing its internal structure and determining if there is a correlation between the induced pain and the patient's usual symptomatology.

Presently, spinal fusion is the recognized surgical technique for the treatment of degenerative disc problems, including discogenic low back pain, after failure of conservative treatments. Its efficacy is, however, uncertain. The assessment of intradiscal electrothermal therapy for the treatment of discogenic low back pain therefore falls within an area of therapeutic uncertainty, where clinical judgment cannot always be supported by scientific evidence.

INTRADISCAL ELECTROTHERMAL THERAPY

Intradiscal electrothermal therapy involves the percutaneous insertion, under local anesthesia and fluoroscopic guidance, of a catheter into the intervertebral disc suspected of being the source of the pain. A heating element at the tip of the catheter gradually increases the temperature to 90°C for about 17 minutes. This procedure, which is performed on an outpatient basis, takes about 90 minutes. The patient should wear a lumbar support for six to eight weeks and undergo a physiotherapy program.

RESULTS

Over the past few years, a number of systematic health technology assessments have examined the efficacy and safety of intradiscal electrothermal therapy. Recent reports identified a small randomized study, a non-randomized, controlled study, and several case series. Our own literature search, which continued up to April 2005, did not identify any other relevant studies. The efficacy evidence for this technology is therefore limited. In addition, the evidence on this procedure is difficult to interpret because of the natural history of chronic discogenic low back pain, the difficulty in assessing pain, the potential for a placebo effect, and the lack of long-term efficacy data.

Given the weakness of the evidence, a number of assessments recommend not including intradiscal electrothermal therapy as an insured service, except in a research setting. However, the National Institute for Clinical
Excellence (NICE) in the United Kingdom states that clinicians wishing to use this procedure should make special arrangements for consent and for audit. In Québec, this type of practice framework corresponds to the classification of innovative technology. As for the safety of this procedure, all the assessments performed thus far conclude that it is acceptably safe.

In Québec, it seems that intradiscal electrothermal therapy is used only in Montréal. One private medical clinic offers this treatment to patients covered by the Commission de la santé et de la sécurité du travail (CSST) on the basis of a reimbursement rate of $4,820, which includes all the costs, except the physician's professional services. The Radiology Department at the Centre hospitalier de l’Université de Montréal (CHUM) offers this procedure to patients covered by the public plan.

CONCLUSIONS

In order for a technology to be medically recognized, a judgment must be made about the level of evidence required for it to move from an experimental status to an innovative status. This judgment takes into account both the uncertainties regarding its efficacy and safety, and the necessity to sustain innovation to improve the quality of care. Especially in situations where the new technology is used to treat serious diseases for which there are few or no alternatives, assigning innovative status can be considered reasonable, even if this decision is based on limited evidence. However, this approval should be conditional upon field research being conducted to assess the effectiveness of the technology.

In the present case, the lack of other proven treatments constitutes an argument in favour of assigning an innovative status to intradiscal electrothermal therapy for the treatment of discogenic low back pain that does not respond to any type of conservative treatment, in particular, intensive multidisciplinary therapy. In addition, intradiscal electrothermal therapy is a much less invasive procedure than spinal fusion, which is presently considered an accepted technology, even if the evidence regarding its efficacy hardly seems any better than that for electrothermal therapy.

The decision to include this technology as an insured service should be conditional upon it being used by appropriately trained physicians in medical settings where continuous evaluation and research are conducted and upon the creation of clinical registries for evaluating its effectiveness in Québec. It would be desirable to include in these registries the spinal fusions performed for the treatment of chronic low back pain, in order to document their effectiveness as well and to improve the overall quality of the treatment of chronic back pain in Québec. These registries could be under the responsibility of university hospitals and of the integrated university healthcare networks, which are presently being implemented in Québec.
# TABLE OF CONTENTS

MISSION ................................................................................................................................. i
FOREWORD ........................................................................................................................... iii
ACKNOWLEDGEMENTS ......................................................................................................... iv
SUMMARY .......................................................................................................................... v

1 INTRODUCTION .................................................................................................................. 1

2 LOW BACK PAIN ................................................................................................................ 2
   2.1 Acute low back pain ....................................................................................................... 2
   2.2 Chronic low back pain ................................................................................................ 2

3 DISCOGENIC LOW BACK PAIN ....................................................................................... 3
   3.1 Diagnosis .................................................................................................................... 3
   3.2 Treatment .................................................................................................................. 3

4 DESCRIPTION OF THE TECHNOLOGY .......................................................................... 5

5 EFFICACY AND SAFETY .................................................................................................. 6
   5.1 Method ...................................................................................................................... 6
   5.2 Efficacy results ......................................................................................................... 6
   5.3 Safety results .......................................................................................................... 9

6 THE SITUATION IN QUÉBEC ......................................................................................... 10

7 CONCLUSIONS ............................................................................................................... 11

ANNEXE A STATUS OF HEALTH TECHNOLOGIES: AETMIS CLASSIFICATION .............. 12
REFERENCES ...................................................................................................................... 13

Table 1 Systematic reviews by HTA agencies ..................................................................... 7
INTRODUCTION

This brief was prepared at the request of the Régie de l’assurance maladie du Québec (RAMQ), which wanted to know if intradiscal electrothermal therapy for the treatment of chronic low back pain "should still be considered experimental and, if so, what the prospects are of it becoming medically recognized". This question first arose as result of special authorization requests for treatment outside Québec: If the requested care is not provided in Québec and if prior authorization is granted, the patient is entitled to a reimbursement of his or her outlays. However, since this technology is now available in Québec, the RAMQ has received a request to establish a code and fee for this professional service.

The purpose of this assessment is therefore to determine if the currently available efficacy and safety evidence for intradiscal electrothermal therapy is sufficient for this treatment modality to no longer be considered experimental (see Appendix A). Brief information will first be presented on the condition treated with this technology, namely, discogenic low back pain, then on the technology per se. We will also present the results of the scientific literature review, then examine the Québec context in order to formulate relevant conclusions.
LOW BACK PAIN

Back pain has been afflicting mankind for thousands of years. The first description of acute low back pain is from a papyrus dating back to 1500 BC, and already 25 centuries ago Hippocrates described sciatica. Today, low back pain constitutes a heavy burden in terms of disabilities, suffering, and economic impact for the patient [Waddell and Schoene, 1998], the family [Strunin and Boden, 2004] and society [Nachemson, 2004a]. Although the problem is not new, the diagnostic and therapeutic approaches have evolved with the advances of modern medicine [Allan and Waddell, 1989].

2.1 ACUTE LOW BACK PAIN

Most low back pain is of short duration. According to a systematic review of prospective studies, 82% of patients (95% confidence interval [CI]: 73% to 91%) who were off work returned to work within one month, and 93% returned in three to six months (95% CI: 91% to 96%). However, 73% of the patients experienced at least one recurrence in the 12 months following the first episode (95% CI: 59% to 88%) [Pengel et al., 2003]. An extensive diagnostic investigation is seldom indicated for acute low back pain [Carragee and Hannibal, 2004]. For patients in the subacute stage (pain that lasts one to three months), a biopsychosocial approach with multidisciplinary management substantially helps reduce the risk of acute low back pain becoming chronic [Waddell and Schoene, 1998].

2.2 CHRONIC LOW BACK PAIN

Chronic low back pain (pain persisting for more than three months) poses a substantial diagnostic and therapeutic challenge [ANAES, 2000a]. The therapeutic approaches are as numerous as they are controversial, but an evidence-based medicine approach is increasingly recommended [Bogduk and McGuirk, 2002; ANAES, 2000a]. Unlike acute low back pain, there are few treatment algorithms for the chronic forms [Bogduk, 2004]. Intensive multidisciplinary therapy should nonetheless be proposed to all patients, and it is only when such therapy fails that more extensive efforts should be made to establish a specific diagnosis. It should be noted that a pathoanatomical diagnosis is often requested in a medicolegal context, for example, in connection with an insurance claim. Bogduk [2004] suggests a treatment algorithm for chronic low back pain that contains a decision node for determining if a specific diagnosis is necessary. A thorough diagnostic investigation may lead to a diagnosis of chronic discogenic low back pain.
DISCOGENIC LOW BACK PAIN

Discogenic low back pain, a symptomatic degeneration of intervertebral discs, is a clinical entity that belong to a spectrum of conditions associated with degenerative changes in the lumbar spine [Crock, 2004]. The pain arises directly from one or more intervertebral discs, with no nerve root compression. The source of the pain is attributed to the outer third of the fibrous ring of the disc, which contains nociceptors. The outline of the disc remains intact, but the disc is characterized by internal disruption due to radial annular tears [Anderson, 2004; Schwarzer et al., 1995].

Internal disc disruption results from degenerative changes often associated with aging. The intervertebral disc is an avascular structure consisting of a peripheral fibrous ring, an inner pulpy nucleus, and cartilaginous plates attached to the adjacent vertebrae. The entire disc receives nutrients through these plates. A decrease in this diffusion function of the plates, due either to degeneration or to microfractures, seems to be the cause of degenerative changes in the disc: a decrease in the proteoglycan and, therefore, water content, changes in the distribution of mechanical forces, and the occurrence of radial annular tears [Biyani and Andersson, 2004; Kaigle Holm and Holm, 2004].

3.1 DIAGNOSIS

Unlike most other degenerative diseases of the lumbar spine, clinical examination, standard x-rays or CT scans are often normal for discogenic low back pain [Crock, 2004]. Magnetic resonance imaging (MRI) shows degenerative disc changes but does not confirm the clinical relevance of those changes. Thus, in an asymptomatic population similar to the population of patients with chronic lumbar pain, up to 76% of the MRI are abnormal [Sachs and Ohnmeiss, 2003]. In a group of patients aged 50 and over, the MRI examinations showed degenerative changes in the lumbar discs in 90 to 100% of the subjects, and internal disruptions (radial annular tears) in 20 to 50% of the cases [Dietemann, 2004].

The diagnosis of internal disc disruption depends on the results of a provocative discography [Schwarzer et al., 1995]. The injection, under low pressure, of contrast material into the disc, often in combination with computed tomography, permits to visualize its internal structure and to determine if there is a correlation between the induced pain and the patient's usual symptomatology [Anderson, 2004; Guyer et al., 2003]. According to the taxonomy of the International Association for the Study of Pain, a positive provocative discography requires that the pain be reproduced and that computed tomography reveal internal disc disruption, provided that a control stimulation of at least one adjacent disc fails to reproduce pain [Grönblad, 2004]. A number of authors recommend to first identify, by MRI, the discs exhibiting degenerative changes and then confirm the clinical significance of these changes by provocative discography [Safuddin, 2004; Guyer et al., 2003].

3.2 TREATMENT

The efficacy of the surgical treatment of chronic low back pain after the failure of conservative treatments is uncertain. Presently, spinal fusion is the generally recognized surgical technique for the treatment of degenerative disc problems [Gunzburg et al., 2004; ANAES, 2000b]. A critical review published in 1995 concludes that "the literature does support the use of spinal fusion in several degenerative disorders of the spine. In many instances, however, fusion surgery is performed based more on clinical anecdote than a rigorous scientific study. Fur-
Further clarification of specific diagnostic entities should allow controlled studies to delineate more clearly the indications for spinal fusion" [Zdeblick, 1995, p. 133S]. In 2004, a Cochrane Collaboration group conducted a systematic review of the scientific literature on the use of spinal fusion for the treatment of degenerative disc problems and came to the same conclusion: "It is encouraging that several RCTs recently have been published, but it still remains difficult to define appropriate treatment for any specific clinical pathology. In no circumstance can we reach even a ‘moderate’ rating of scientific evidence for any intervention" [Gibson and Waddell, 2004, p. 299].

The assessment of intradiscal electrothermal therapy for the treatment of discogenic low back pain should be viewed within this complex and uncertain context of the treatment of chronic low back pain, where clinical judgment cannot always be supported by scientific evidence [Nachemson, 2004b].
DESCRIPTION OF THE TECHNOLOGY

Intradiscal electrothermal therapy involves the percutaneous insertion, under local anesthesia and fluoroscopic guidance, of a catheter into the intervertebral disc suspected of being responsible for the pain. A heating element at the distal tip of the catheter gradually increases the temperature to 90°C for about 17 minutes, which increases the temperature of the fibrous ring of the disc to about 60°C or 65°C [Endres et al., 2002]. This procedure, which is performed on an outpatient basis, takes about 90 minutes. The patient should wear a lumbar support for six to eight weeks and undergo a physiotherapy program.

The mechanism of action is unknown. It is postulated that heat causes the collagen in the fibrous ring to coagulate or destroys the nociceptors in the disc [Cohen, 2003]. Animal studies do not, however, seem to confirm neither the collagen coagulation theory [Bass et al., 2004] nor the nociceptor destruction theory [Freeman et al., 2003].
5 EFFICACY AND SAFETY

5.1 METHOD

A literature search was performed in the PubMed database,\(^1\) the health technology assessment database of the Centre for Reviews and Disseminations, York University (England),\(^2\) and on the Internet. The articles and reports published up to April 2005 were examined for the purpose of the present assessment.

5.2 EFFICACY RESULTS

Over the past few years, several systematic health technology assessments (HTA) have examined the efficacy and safety of intradiscal electrothermal therapy. Table 1 summarizes the findings of the six latest assessments and indicates the studies included in the analyses. More limited analyses have also been conducted in Denmark [DACEHTA, 2003] and Canada [CCOHTA, 2003]. They are, respectively, a health technology alert and a pre-assessment.

As a general rule, the assessments have analyzed the same set of studies, with a few variants, taking the year of publication into account. Efficacy studies of intradiscal electrothermal therapy are few in number and mainly of the case series type. The latest assessment, which was conducted by the National Institute for Clinical Excellence in the United Kingdom, presents these different analyses in detail [NICE, 2004a].

According to the data analyzed by NICE, most patients report a reduction in pain on a visual analogue scale (VAS). The only randomized study involved a small number of patients: 37 treated, 32 of whom were included in the analysis, and 27 controls, 24 of whom were included in the analysis [Pauza et al., 2004]. Randomized studies of invasive procedures encounter major difficulties, and the study by Pauza et al. was no exception. Indeed, 4523 people answered the recruitment announcements made in the media, but 3163 (70%) of them declined to participate in the study when the study protocol was explained to them. Of the 1360 patients who were willing to participate, 1100 did not meet the inclusion criteria, and 196 had a negative provocative discography.

The subjective evaluation of the patients at six months after the procedure found that there was an improvement in 78% (25/32) of the patients who had undergone intradiscal electrothermal therapy compared to 46% (11/24) of the control group. Pain worsened in 6% of the patients in the treated group and in 33% of the subjects in the placebo group, and it remained the same in 16% (5/16) and 21% (5/21) of them, respectively. These differences in proportions in all the categories are significant (Fischer’s test: \(p = 0.037\)). The results show that the procedure could not only reduce pain in certain patients, but also prevent it from worsening. However, if the recommended criterion of an improvement greater than 50% is taken into account, the difference between the two groups is hardly notable: 38% in the treated group and 33% in the control group.

---

\(^1\) The following statement was used when searching in the PubMed literature database: ((discal* OR intradiscal* OR intradiskal OR intervertebral OR discogenic OR disco- genique) AND (thermocoagulation OR therapy OR therapie OR electrothermal* OR thermal* OR electrocoagulation OR electric OR heat OR electrotherm* OR electrique)) OR ideta OR idta OR idet OR pirft OR diskogra* OR discoGRA*

\(^2\) This database can be consulted at http://www.york.ac.uk/inst/crd/htahp.htm.
<table>
<thead>
<tr>
<th>REFERENCE (COUNTRY)</th>
<th>EFFICACY STUDIES EXAMINED</th>
<th>FINDINGS</th>
</tr>
</thead>
</table>
| Institute for Clinical Systems Improvement (ICSI) et al., 2002 (United States) | *Nonrandomized, controlled study:* Karasek and Bogduk, 2000  
*Case series:* Derby et al., 2000; Saal and Saal, 2000a; 2000b | ▪ Low level of evidence  
▪ No recommendation regarding the technology’s status |
| Medical Services Advisory Committee (MSAC), 2002 (Australia) | *Nonrandomized, controlled studies:* Bogduk and Karasek, 2002; Karasek and Bogduk, 2000  
*Case series:* Endres et al., 2002; Saal and Saal, 2002; Derby et al., 2000; Saal and Saal, 2000a; 2000b | ▪ Low level of evidence  
▪ Experimental technology |
| ASERNIP-S, 2003 (Australia) | *Randomized study:* Pauza et al., 2002 (conference abstract)  
*Nonrandomized, controlled study:* Karasek and Bogduk, 2000  
*Case series:* Endres et al., 2002; Saal and Saal, 2002; Derby et al., 2000; Saal and Saal, 2000a; 2000b; Singh, 2000; and 12 other references in the form of conference abstracts | ▪ Short-term efficacy, limited evidence  
▪ No recommendation regarding status |
| Washington State Department of Labor and Industries, 2003 (United States) | *Randomized study:* Pauza et al., 2004  
*Nonrandomized, controlled study:* Bogduk and Karasek, 2002  
*Case series:* Lutz et al., 2003; Endres et al., 2002; Gerszten et al., 2002; Saal and Saal, 2002 | ▪ Insufficient level of evidence  
▪ Experimental technology |
| Technology Evaluation Center and Blue Cross Blue Shield Association, 2004 (United States) | *Randomized study:* Pauza et al., 2004  
*Nonrandomized, controlled study:* Karasek and Bogduk, 2000  
*Case series:* Lutz et al., 2003; Endres et al., 2002; Gerszten et al., 2002; Saal and Saal, 2002; Spruit and Jacobs, 2002; Derby et al., 2000; Saal and Saal, 2000a; 2000b; Singh, 2000 | ▪ Low level of evidence  
▪ Experimental technology |
| National Institute for Clinical Excellence (NICE), 2004a (United Kingdom) | *Randomized study:* Pauza et al., 2004  
*Nonrandomized, controlled studies:* Bogduk and Karasek, 2002; Karasek and Bogduk, 2000  
*Case series:* Cohen, 2003; Lutz et al., 2003; Gerszten et al., 2002; Saal and Saal, 2002; Derby et al., 2000; Saal and Saal, 2000a; 2000b | ▪ Persistent uncertainties regarding its efficacy  
▪ Innovative technology |
In two case series, the experience of a pain-relieving effect ranged from 48% (38/79) after six months [Cohen, 2003] to 72% (42/58) after 24 months [Saal and Saal, 2002]. There are also data indicating an improvement in physical function, bodily pain and disability scores after the procedure. However, these improvements were not measured against a control group, except in the randomized study by Pauza et al. [2004].

Two recent articles were not included in the NICE analysis because the study populations were too narrow for the results to be generalized to the population at large. The articles concern a case series involving American soldiers on active duty [Freedman et al., 2003] and a study of workers’ compensation records in the United States [Webster et al., 2004].

Although the description of another case series [Davis et al., 2004] was included in the appendix to the British report after the consultation period, it was not considered in its conclusions. The study analyzed the outcomes of intradiscal electrothermal therapy in 60 patients referred by 17 centres. The efficacy analysis concerns the outcomes in 38 patients. Eight declined to answer the questionnaire because they were involved in a work accident and injury claim, eight could not be reached, and six had to undergo lumbar surgery after electrothermal therapy. The follow-up was 6 to 38 months, with a mean of 20.4 months. Pain subsided within 12 months in 39% of the 38 patients, remained stable in 29% of the subjects and increased in 29% of them. Fifty percent of the patients were not satisfied with the outcomes, 37% were satisfied and 13% were undecided. On the other hand, 53% indicated that they would choose this treatment if they were in the same situation again, 31% indicated that they would not, and 16% were not sure. The spinal fusion rate was estimated at 15% at one year and at 30% at two years using the Kaplan-Meier method.

NICE [2004b] states that the evidence from the studies examined is difficult to interpret because of the natural history of chronic discogenic low back pain, the difficulty in assessing pain and the potential for a placebo effect. It also notes that there is a lack of long-term efficacy results. These observations lead both NICE and the other assessment agencies to conclude that the level of efficacy evidence remains low or insufficient. This is also the conclusion that the Canadian and the Danish assessment agencies arrive at in their brief assessments [CCOHTA, 2003; DACEHTA, 2003].

This uncertainty concerning the efficacy of intradiscal electrothermal therapy has been invoked by four of the agencies (including the Danish one) to justify their assigning experimental status to it and the decision not to include it as a service covered by public or private insurance plans, except in a research setting.

On the other hand, NICE [2004b] does not completely close the door to this technology. It states that clinicians wishing to use this procedure should make special arrangements for consent and for audit. In Québec, this type of practice framework corresponds to the classification of innovative technology (see Appendix A). This particular position taken by NICE, which is nonetheless based on an assessment of the methodological quality and findings of the main studies similar to the other agencies’ assessments, seems to stem from different requirements in terms of the level of evidence needed for a technology to move from experimental to innovative status.

Since the publication of the NICE report in August 2004, no new publication on the efficacy of intradiscal electrothermal therapy has been identified. One still-unpublished study involving a small number of Québec patients obtained interesting results: pain completely or almost completely disappeared after 12 months in 42% (5/12) of the patients [Filiatrault et al., 2002].
5.3 SAFETY RESULTS

All of the evaluations conducted thus far on the safety of intradiscal electrothermal therapy conclude that it is a safe procedure. According to NICE's assessment, which is similar to that of the other agencies, the complications are mostly transient, and their incidence ranges from 0% (0/58) [Saal and Saal, 2002] to 15% (5/33) [Lutz et al., 2003]. The transient complications observed were increasing radicular pain (15%: 5/33) [Lutz et al., 2003], paresthesia and numbness in the thighs (3%: 2/79) and foot drop (1%: 1/79) [Cohen, 2003]. One study reports a cerebrospinal fluid leak in one patient. However, there have been two case reports of cauda equina syndrome and two of vertebral osteonecrosis [NICE, 2004b].
In Québec, it appears that intradiscal electrothermal therapy is used only in Montréal, at the Institut de physiatrie du Québec, a private medical clinic, and in the Radiology Department of the Centre hospitalier de l'Université de Montréal (CHUM). Following an agreement concluded between the Ministère de la Santé et des Services sociaux and the workers’ health and safety board (CSST), intradiscal electrothermal therapy has been reimbursable since June 2003 for patients covered by the CSST. The reimbursement rate, which includes all of the costs, except the physician's professional services, has been $4,820 since April 15, 2004. The Institut de physiatrie du Québec is currently the only place in Québec that offers this treatment to patients covered by the CSST. Physicians at the Institut de physiatrie du Québec are still not paid for this procedure, since the fee for this professional service has to be negotiated with the Fédération des médecins spécialistes du Québec (FMSQ). Negotiations concerning the fee for this service will start after this brief is submitted to the Régie de l’assurance maladie du Québec (RAMQ). Dr. Filiatrault, of the Institut de physiatrie du Québec, has requested, through CHUM's Department of Medicine, that the procedure be offered to patients covered by the public insurance plan. This request has, in principle, been approved, but the necessary funding has not been provided.

CHUM's Radiology Department presently offers intradiscal electrothermal therapy to patients covered by the public plan. Following an assessment project funded within the framework of university hospitals' new technology assessment mandate, the necessary equipment was purchased in May 2002, and the allotted budget has been used to treat about ten patients. Since 2003, CHUM's Radiology Department has been funding the procedure for patients covered by the public plan, but no analysis of the assessment project has yet been performed. A joint committee of the Departments of Medicine and Radiology will be set up to harmonize patient selection and the use of this treatment modality by CHUM physiatrists and radiologists.

Decisions concerning the practice of intradiscal electrothermal therapy in Québec bring out the contradictions in policies regarding the status of technologies. Thus, the Ministère de la Santé et des Services sociaux is signing an agreement with the CSST concerning the reimbursement of this technology, while the RAMQ is wondering if it is medically recognized. In addition, within a given university hospital, policies on intradiscal electrothermal therapy differ from one department to the next. This situation clearly emphasizes the need for more consistency in the decisions within the healthcare system, which should be supported by adequate data on the efficacy, safety and cost of a given technology. The development of the health technology assessment function at university hospitals seems essential in order to improve this situation.

It appears that the practice of intradiscal electrothermal therapy in Québec is one of the most active in Canada. The Canadian division of Smith & Nephew, which markets intradiscal electrothermal therapy equipment worldwide, plans to promote this technology more actively.

---

3. Personal communications (e-mail and telephone) with Dr. Luc Marcoux, Medical Services Division, CSST, September 2004.
4. Personal communications (e-mail and telephone) with Dr. Serge Lafrance, Medical, Dental and Optometrical Affairs Division, RAMQ, September 2004.
5. Telephone communication with Dr. Marc Filiatrault, Institut de physiatrie du Québec, Montréal, September 2, 2004.
6. Telephone communication with Nicole Langlois, Manager, Radiology Department, CHUM, January 20, 2005.
8. Personal communication with Dr. Marc Filiatrault, February 13, 2005.
CONCLUSIONS

Depending on the different systematic assessments of this technology by American, Australian and British agencies, the status of intradiscal electrothermal therapy corresponds to an experimental technology or an innovative technology (see Appendix A). What should the framework be for using intradiscal electrothermal therapy in Québec?

According to a discussion paper from Alberta’s technology assessment agency, the decision to cover emerging technologies should take into account both the uncertainties regarding their efficacy and safety, and the necessity to sustain innovation to improve the quality of care. Especially in situations where the new technology is used to treat serious diseases for which there are few or no alternatives, moving it from experimental status to innovative status can be considered reasonable, even if this decision is based on limited evidence. However, approving it as an innovative technology can be conditional on field research being conducted to assess the effectiveness of the technology [Hailey and Harstall, 2001].

In the present case, the lack of other proven treatments is an argument in favour of assigning innovative status to intradiscal electrothermal therapy for the treatment of discogenic low back pain that does not respond to any type of conservative treatment, in particular, intensive multidisciplinary therapy. In addition, intradiscal electrothermal therapy is a much less invasive procedure than spinal fusion, which is presently considered an accepted technology, even if the evidence regarding its efficacy hardly seems any better than that for electrothermal therapy. Lastly, electrothermal therapy could be proposed to patients who choose not to undergo surgery.

However, it is up to the Ministère de la Santé et des Services sociaux (MSSS) to determine if the data on the efficacy, cost and clinical need provided in this brief is sufficient to justify no longer considering this technology experimental. If it does, the particulars of the professional service in question and of the fee relating thereto will need to be negotiated with the FMSQ-MSSS-RAMQ Technical Committee before it can be included in the MSSS-FMSQ agreement. Medical specialists can then be remunerated, which will have an impact on the offer of this technology to Québec patients.

The decision to include this technology as an insured service should be conditional on its use by appropriately trained physicians at medical settings where clinical research is conducted and on the creation of clinical registries for evaluating its effectiveness in Québec. It would be desirable to include in these registries the spinal fusions performed for the treatment of chronic low back pain, in order to document their effectiveness as well and to improve the quality of the treatment of chronic back pain in Québec. These registries could be under the responsibility of university hospitals and of the integrated university healthcare networks, which are presently being implemented in Québec.
AETMIS has developed the following classification to identify the status of health technologies under review [CETS, 1994]:

**Experimental status**

The term “experimental” will be used here to describe a procedure whose effectiveness has yet to be established. Such a procedure should therefore not be used in health-care facilities, except in the context of research projects.

**Innovative status**

The term “innovative” will be used to describe a technology which has passed the experimental stage and whose effectiveness has been established. However, because of a lack of experience, certain indications for its use and various aspects of its application are not yet clearly defined. To gain further knowledge of such technology, it would be important to gather systematically all the information acquired from its utilization and to communicate it to the medical community in the form of a clinical research report or systematic review or to an appropriate registry. To further these objectives and to prevent its premature widespread use, such technology should be restricted to certain authorized university hospitals which have the necessary resources and knowledge.

**Accepted status**

The term “accepted” will describe a well-established technology for which there is a long history of use and a knowledge of, or failing that universal acceptance of, its effectiveness in all its applications.
REFERENCES


Filiatrault M, Bouthillier C, Fortin L. Projet de recherche-pilote sur la thermoplastie annulaire (IDET). Presentation at the Fifth International Forum for Back Pain Research in Primary Care, Montréal, May 2002. Available from the author (marc.filiatrault@umontreal.ca).


Agence d’évaluation des technologies et des modes d’intervention en santé

Québec