

Intradiscal electrothermal therapy for discogenic low back pain

Summary

AGENCE D'ÉVALUATION DES TECHNOLOGIES
ET DES MODES D'INTERVENTION EN SANTÉ

Intradiscal electrothermal therapy for discogenic low back pain

Technical Brief prepared for AETMIS
By Reiner Banken

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Scientific review

Dr. Véronique Déry, MD, MSc, General and Scientific Director
Jean-Marie Lance, MSc, Senior Scientific Advisor

Translation

Mark Wickens, PhD, Certified Translator

Proofreading

Suzie Toutant

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
Web site: www.aetmis.gouv.qc.ca
E.mail: aetmis@aetmis.gouv.qc.ca
www.aetmis.gouv.qc.ca

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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—is 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 put in the same category 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 his 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

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Dr. Marc Filiatrault

Physiatrist, *Hôpital Notre-Dame* (CHUM), and *Institut de psychiatrie 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.

SUMMARY

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 completely based on 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 nonrandomized, 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 placebo effect, and the paucity 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 take special arrangements for consent and for audit or research. 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 other treatments, 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 determine 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 health-care networks (IUHNs), which are presently being implemented in Québec.

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