The ^{13}C-Urea Breath Test for Detection of *Helicobacter pylori*

Potential Applications in Québec

SUMMARY

AGENCE D'ÉVALUATION DES TECHNOLOGIES
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Québec

The ^{13}C-Urea Breath Test for Detection of *Helicobacter pylori*

Potential Applications in Québec

Technology brief prepared for AETMIS
by Lonny Erickson

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Scientific review
Alicia Framarin, MD, MSc, Deputy Scientific Director
Jean-Marie Lance, MSc, Senior Scientific Advisor

Proofreading
Frédérique Stephan
Suzie Toutant

Page layout
Jocelyne Guillot

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

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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.

FOREWORD

THE ^{13}C-UREA BREATH TEST FOR DETECTION OF *HELICOBACTER PYLORI*: POTENTIAL APPLICATIONS IN QUÉBEC

Infection with *Helicobacter pylori*, a bacterium which plays an important role in the pathogenesis of gastroduodenal disorders, is a common problem affecting 20% to 40% of Canadians. The usual clinical manifestation of this infection is dyspepsia, meaning one or more symptoms referable to the upper gastrointestinal tract. Detection of *H. pylori* infection is therefore essential to dyspepsia management.

Many methods have been developed to detect *H. pylori*. Among invasive techniques, endoscopy with biopsy is recognized as an effective method, although expensive and uncomfortable for patients. Other less invasive detection methods have been developed, notably urea breath tests. In Québec, the urea breath test using radioactive (^{14}C) carbon is used in hospitals with nuclear medicine departments. Another urea breath test exists which is non-radioactive, using a heavy isotope of carbon (^{13}C). This test was added to the list of publicly covered laboratory procedures in April 2005.

At the request of the Québec Ministry of Health and Social Services, this technology brief examines different methods for detection of *H. pylori* as well as the pertinence of increased utilization of the ^{13}C-urea breath test in Québec.

Results of the literature review confirm the superiority of urea breath tests compared to other detection methods for *H. pylori* and also show that the ^{13}C-urea breath test is a proven technique that is easy to administer at a reasonable cost. The fact that this test is non-radioactive allows patients suffering from dyspepsia to have access to a non-invasive diagnostic test across the province.

Therefore, AETMIS considers that the ^{13}C-urea breath test should be available in all regions of Québec in health-care institutions where quality of administration can be ensured. In addition, clinicians should be informed of the availability of the test and also participate in the definition of optimal conditions of use of this test. Finally, due to the expected evolution of testing methods for *H. pylori* in the near future, this area should be periodically re-evaluated in light of new developments.

In producing this technology brief, AETMIS aims to contribute to the improvement of health of persons suffering from dyspepsia in Québec.

Dr. Luc Deschênes
President and Chief Executive Officer

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Colette Deslandres, MD
Pediatric Gastroenterologist, Department of Gastroenterology, Hepatology and Nutrition, Hôpital Sainte-Justine, Montréal, Québec.

Joël Desroches, MD
Nuclear Medicine Specialist, Centre hospitalier régional de Trois-Rivières, Trois-Rivières, Québec

Carlo Fallone, MD
Director, Division of Gastroenterology, McGill University Health Centre (MUHC), Royal Victoria Hospital, Montréal, Québec

Daniel Picard, MD
Nuclear Medicine Specialist, Centre hospitalier universitaire de Montréal (CHUM), Hôpital Saint-Luc, Montréal, Québec

Scott Whittaker, MD
Gastroenterologist, Clinical Assistant Professor, University of British Columbia, Vancouver, British Columbia

DISCLOSURE OF CONFLICT OF INTEREST

None declared.

SUMMARY

INTRODUCTION

Helicobacter pylori bacteria plays an important role in the pathogenesis of gastroduodenal disorders. This is usually observed as dyspepsia, which refers to one or more symptoms referable to the upper gastrointestinal tract. The prevalence of *H. pylori* infection in Canadians is estimated to be between 20% and 40%. This technology brief, conducted at the request of the Québec Ministry of Health and Social Services (MSSS), examines different detection methods for *H. pylori* available for patients suffering from dyspepsia as well as the relevance of increasing utilization of the ^{13}C-urea breath test in Québec.

MANAGEMENT STRATEGIES FOR DYSPEPSIA

Endoscopy is the gold standard for diagnosis of *H. pylori* infection, permitting the collection of samples for biopsy to confirm infection and initiate eradication therapy when results are positive.

There is currently a great deal of interest in the non-invasive 'test and treat' strategy, which consists of non-invasive testing for *H. pylori* followed by appropriate treatment when results are positive. This strategy is recommended by recent clinical guidelines and Canadian and international consensus conferences. A second test to confirm eradication of *H. pylori* may be conducted following treatment.

NON-INVASIVE METHODS FOR DETECTION OF *H. PYLORI*

Non-invasive testing methods for detection of *H. pylori* or confirmation of eradication include: 1) antibody tests (in serum, saliva or blood); 2) antigen tests (in stools, saliva or urine); and 3) radioactive or non-radioactive urea breath tests.

Antibody detection tests are available in Québec at low cost. They have a good negative predictive value, but also have a high rate of false-positive results because antibodies persist for a long period of time after the bacteria have been eradicated. In addition, they are not appropriate to confirm eradication due to this persistence of antibodies even after active infection has been eliminated.

Many antigen tests also exist, however the test for which there is currently the most interest is the detection of antigens in stool samples by enzyme immunoassay technique. While this test has good performance at a reasonable cost, doubts exist regarding patient and clinician compliance and actual performance, particularly with regard to interlaboratory variability.

The urea breath test is based on analysis of samples of exhaled air before and after ingestion of urea containing specially labelled carbon. H. pylori produces an enzyme, called urease, which converts urea into carbon dioxide and ammonia. The carbon dioxide is excreted in air exhaled from the lungs, and the quantity of labelled carbon can be measured in a sample of this exhaled air to determine the presence of active H. pylori infection in the stomach. Carbon in the urea can be labelled with a radioactive isotope, carbon 14, or a heavy stable isotope, carbon 13. The breath test performs extremely well, regardless of the labelling method used.

COMPARISON OF RADIOACTIVE (^{14}C) AND NON-RADIOACTIVE (^{13}C) VERSIONS OF THE UREA BREATH TEST

The performance of these two tests is virtually identical, therefore practical considerations should determine the choice between either one in a given context for a particular patient.

The radioactive ^{14}C-urea breath test must be administered in hospitals with nuclear medicine departments, which restricts its accessibility. Despite the fact that the actual dose of radiation is very low, this test is contra-indicated for pregnant women and young children. In Québec, this test is publicly covered and offered in several hospitals. The total volume of tests administered in Québec is unknown, however it is known that some large hospitals in Montréal conduct over 1000 tests per year. The MSSS assigns a value of 45 technical units in the nuclear medicine department to this test (the monetary value of a technical unit varies between hospitals).

The ^{13}C-urea breath test was added to the list of publicly covered laboratory tests in Québec in April of 2005. Until recently, only private laboratories used this test. Currently, this test is not very well known in Québec. Due to the fact that this test is not radioactive, it can be widely administered in all regions of Québec. Samples can be sent for analysis to a laboratory with a mass spectrometer, which is required for analysis. The weighted value in biochemical laboratory units assigned to this test by the MSSS is equal to 40 (it is estimated that one unit equals C$1).

Precise estimation of costs of urea breath tests in Québec is beyond the scope of this technology brief. Published Canadian studies have used values ranging from $40 to $120 for the ^{13}C-urea breath test. However, methods for calculation of costs vary between studies, therefore caution must be applied in the interpretation of these values.

CONCLUSIONS AND RECOMMANDATIONS

Results of the literature review confirm the superiority of urea breath tests compared to other detection methods for *H. pylori* and indicate that the ^{13}C-urea breath test is a proven technique, easy to administer, at a cost quite similar to that of the ^{14}C-urea breath test. The fact that the ^{13}C-urea breath test is not radioactive allows patients suffering from dyspepsia to have access to a non-invasive test across the province. AETMIS recommends that the ^{13}C-urea breath test be made available in all regions of Québec, and also proposes the following to ensure optimal use of this test:

- Patients in public health-care institutions in all regions should have access to the ^{13}C-urea breath test.
- Centres that administer the ^{13}C-urea breath test must respect proper procedures and ensure quality control.
- Clinicians should be informed of the availability of this test.
- Clinicians involved (gastroenterologists, pediatricians, general practitioners) should define optimal use of this test for diagnosis and confirmation of eradication of *H. pylori* in current clinical practice.
- Due to the expected evolution of various testing options for *H. pylori*, developments in all types of invasive and non-invasive testing in this area should be periodically re-evaluated in collaboration with experts in this area in Québec (members of the Canadian Helicobacter Study Group, for instance).

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