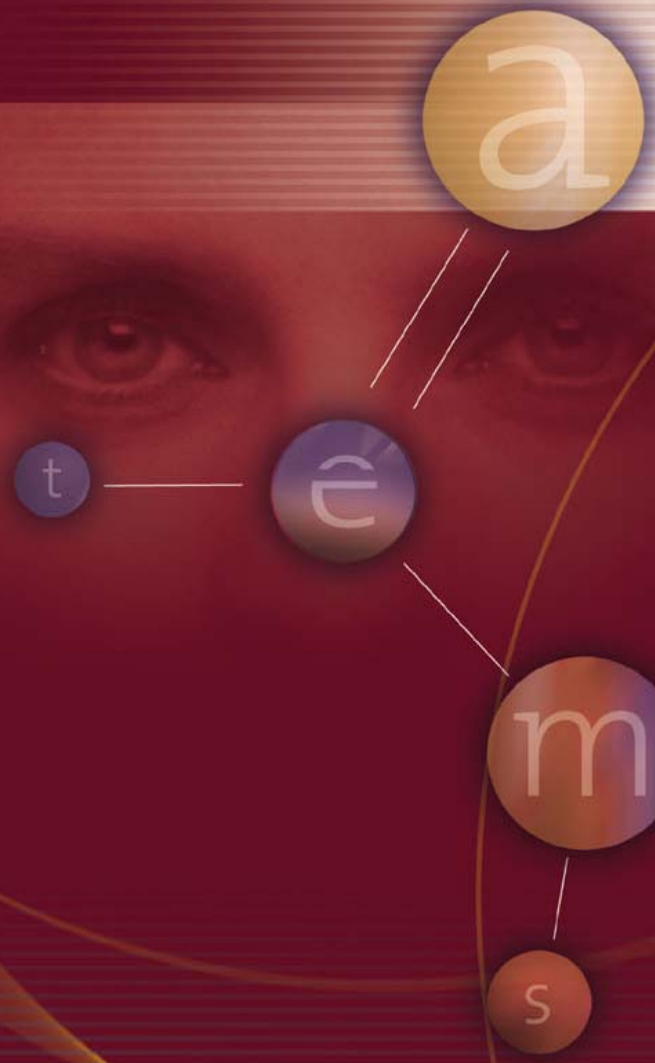
An Economic Analysis of Drug Eluting Coronary Stents

A Québec Perspective

SUMMARY



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

Québec

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A Québec Perspective

SUMMARY

Report prepared for AETMIS
by James Brophy and Lonny Erickson

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

ECONOMIC EVALUATION OF DRUG ELUTING CORONARY STENTS: A QUÉBEC PERSPECTIVE

Heart disease, and particularly coronary artery disease, has a considerable burden of mortality and morbidity in Québec and elsewhere. The problem is often blockage (stenosis) of coronary arteries which can be treated by reduction of risk factors, various medications and revascularization. Restoration of coronary circulation was originally achieved by coronary bypass surgery, however in recent years less invasive techniques such as balloon angioplasty have been developed. This technique involves insertion of a small balloon via a catheter into the artery followed by expansion to open the blocked vessel and placement of metal stents to prevent restenosis. Stents are endoprostheses made of a fine cylindrical mesh of stainless steel placed inside coronary arteries to keep the affected sections of these vessels (dilated by balloon angioplasty) open. These stents are now used in most interventions of this type in Québec, however a certain number of patients may still develop restenosis requiring additional interventions.

A recent technological advance is the development of pharmaco-active stents which reduce risk of restenosis; however they do not reduce the risk of death or myocardial infarction compared to bare metal stents. These drug-eluting stents are being increasingly promoted but some controversy exists as to how many patients should receive these more effective, yet more expensive devices.

In this context, the Québec Ministry of Health and Social Services requested that the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) in collaboration with the *Réseau québécois de cardiologie tertiaire* (RQCT) undertake an assessment of drug-eluting stents. The present report deals with the economic aspects of introducing this device in the health-care system.

The analysis indicates that universal adoption of drug-eluting stents would significantly reduce rates of repeat revascularization interventions in Québec. However, under current epidemiological conditions and purchase costs it would represent a considerable budgetary investment for moderate benefits in terms of avoided revascularization interventions. Because of the relatively low rates of restenosis currently observed in Québec, a much more cost-effective strategy currently would support limited use of drug-eluting stents given to carefully selected high-risk patients across the province, with the remainder of patients continuing to receive bare metal stents.

Systematic data collection on outcomes of patients treated with bare metal and drug-eluting stents is required to guide decision-making in coming years regarding optimal use of this new technology. This is a very rapidly developing area with an almost continuous influx of new information, therefore this issue should be re-examined in 6 to 12 months.

In submitting this report, AETMIS aims to contribute to optimal utilization of various resources in cardiology for the benefit of all affected patients.

Luc Deschênes
President and Chief Executive Officer

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CONFLICT OF INTEREST

None declared.

EXECUTIVE SUMMARY

CONTEXT AND OBJECTIVES

Most percutaneous coronary interventions (PCI) are now performed with the use of coronary stents. These stents are endoprostheses made of a fine cylindrical mesh of stainless steel placed inside coronary arteries to keep the affected sections of these vessels (dilated by balloon angioplasty) open. This technology has led to improvements in the safety of the procedure and to improved outcomes with a decreased incidence of restenosis requiring a repeat revascularization. Despite these improvements, restenosis leading to recurrent symptoms and the need for repeat procedures has remained a vexing problem.

Recent technological advances have led to the development of coronary stents coated with pharmacoactive agents which reduce restenosis. Studies of these drug-eluting stents (DES) have been shown to decrease neointimal proliferation thereby further reducing angiographic restenosis rates and the subsequent need for repeat revascularization procedures. The evidence for the efficacy and safety of this technology in the short to medium term is excellent. However, this new technology is associated with substantial acquisition costs. At the time of writing of this report, a formal cost-effectiveness analysis has not yet been performed.

The present report attempts to quantify the benefits and costs associated with DES technology in order that informed resource allocation decisions may be made. The economic analysis was conducted from the perspective ot the Québec Ministry of Health and Social Services. This report has employed a systematic approach using evidence from both randomized clinical trials and from all-inclusive Québec medico-administrative databases describing local current practice patterns. The fact that objective data have been used to construct a realistic, transparent economic model and to provide Québec data-based estimates (and expected variability ranges for the model parameters) is a major strength of this report.

EFFICACY OF DRUG-ELUTING STENTS

A systematic review of all randomized trials comparing either sirolimus and paclitaxel, the two commercially available products, to bare metal stents has revealed no differences for mortality (Odds Ratio [OR] 1.03, 95% confidence interval [CI]: 0.56-1.92) or myocardial infarction (OR 0.93, 95% CI: 0.63-1.32). Drug eluting stents have been associated with a substantial decrease in the need for repeat target vessel revascularization (OR 0.26, 95% CI: 0.11-0.52). Current repeat revascularization rates in Québec following the use of bare metal stents have been determined from examination of medico-administrative databases (Med-Écho and RAMQ) from 1995 to 2000. During this period, the pooled average rate of a first re-intervention in the 9 months following an initial PCI was 12.8% (95% CI: 10.4-16.0). Most of these reinterventions were PCI (82%), with the remainder being coronary artery bypass grafts (CABG; 18%).

POTENTIAL IMPACT ON HEALTH CARE BUDGET

Based on the current purchase cost of $2,600 for DES, a baseline 9-month restenosis rate of 12.8%, and 14,000 angioplasties performed annually in Québec with an average of 1.7 stents per procedure, 100% substitution of bare metal stents with DES would require an additional $44.9 million of provincial funding. This would be associated with savings of $9.7 million, due to 1 527 fewer repeat revascularizations (of which 82% are PCI and 18% are CABG), leading to a net incremental cost of $35.2 million. Since no lives would be saved nor myocardial infarctions avoided, this benefit would cost $23,067 for each avoided repeat revascularization. Despite the fact that no

reduction in CABG rates was observed in the documented randomized trials, this benefit was included in the economic analysis to reflect the best available clinical data from Québec at the time of writing of this report.

SELECTION OF HIGH-RISK PATIENTS TO RECEIVE DES

This analysis indicates, using the best currently available data, that universal use of DES would require significant additional health care funding even after savings are considered. Therefore, another potential scenario is to offer DES to a limited proportion of patients. In this situation, an optimal rate of DES use and selection criteria for the most deserving patients must be determined. If DES are only available for a limited number of patients, clinicians will naturally try to identify categories of patients at highest risk for restenosis to maximize potential benefit. There are several patient and angiographic features that are associated with increased risk of repeat revascularization, including diabetes, lesion length and vessel diameter. It is currently unknown to what extent high-risk patients prone to repeat revascularization can be identified in Québec. However, observations from medico-administrative databases indicate that diabetics make up 20% of the patient population receiving PCI and have a relative risk (RR) of restenosis 1.53 times that of non-diabetics. Given the presence of other potential clinical features to identify high-risk patients, it seems plausible that experienced clinicians using a combination of clinical and angiographic predictors may be capable of identifying patients with increased RR of 2 to 3.

POTENTIAL RATES OF PENETRATION OF DES

The goal of this report is not to define a specific ceiling for this technology but rather to expose in a transparent fashion the costs and benefits that different penetrations of this technology will produce. An approximate 20-40% level has recently been suggested by an expert panel of Québec cardiologists (associated with the *Réseau québécois de cardiologie tertiaire*) as being clinically appropriate. Given that the baseline 9-month restenosis rate is currently 12.8% with bare metal stents in Québec, applying a policy of allowing for a 20% DES implantation rate to the most deserving patients would assure that most high-risk cases would have access to this technology. If a DES rate of only 10% were provided, costs would be lower; however, many clinically identifiable high-risk patients would not be able to receive DES. Conversely at levels of greater than 30% DES, clinicians would be treating an increasing number of lower risk patients.

COST IMPACT OF TARGETED USE OF DES

Using the 9 month baseline restenosis rate of 12.8%, and a 20% DES penetration rate applied selectively to high risk patients (RR = 2.67), the net incremental cost after allowing for savings due to avoided revascularizations would be $4.7 million with 651 repeat revascularization interventions avoided at an average cost of $7,200 per avoided procedure. Of the avoided repeat revascularizations, 82% would be angioplasties and 18% would be coronary artery bypass surgeries. In this scenario, the breakeven cost, whereby the savings in reduced repeat revascularizations associated with DES completely offsets the additional purchase cost, occurs at a DES purchase price of $1,663. Corresponding breakeven costs would be $1,266 for 60% DES use (with selection of patients with a RR of 1.7 to receive DES) and $1,161 for 100% DES use. As the percentage of DES increases, incremental savings as a percentage of total expenditures fall and the cost per revascularization avoided increases.

LIMITATIONS OF THE CURRENT ANALYSIS

Although this analysis is the most extensive analysis yet performed and tailored to the Québec environment, there are a number of limitations such as the absence of considera-

tion of the impact of additional funding for DES on other potential interventions competing for the same limited budget. Also, the potential for additional benefits of DES due to treatment expansion to include patients not presently eligible for a percutaneous intervention has not been considered. There is also some uncertainty regarding the actual rate of restenosis in Québec with BMS currently used. Also, if patients that otherwise might undergo CABG can be directed to angioplasty due to DES use, then substantial savings could be incurred. Should new evidence become available applicable to the clinical reality in Québec, this model can be easily updated.

IMPLICATIONS

Finally, irrespective of the level of financing adopted for DES, ethical considerations underpinning the universality of our health care system dictate that equally deserving patients should have equal access to this technology. This implies that this technology, at whatever designated level, should be available at all centres performing PCI and that similar selection criteria should be broadly applied to assure equal accessibility according to clinical need and not geographic location. It is also abundantly clear that an evaluation of the local results with DES is necessary to aid future decision-making regarding this technology. Details regarding the implantation of all coated stents should be recorded in a registry to facilitate this evaluation. The *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) and the *Réseau québécois de cardiologie tertiaire* would appear to be ideal guarantors for this registry.

ABBREVIATIONS

AETMIS	*Agence d'évaluation des technologies et des modes d'intervention en santé*
BMS	Bare Metal Stent
CABG	Coronary Artery Bypass Graft
CEDIT	*Comité d'Évaluation et de Diffusion des Innovations Technologiques*
CCN	Cardiac Care Network (Ontario)
CI	Confidence Interval
CCOHTA	Canadian Coordinating Office of Health Technology Assessment
DES	Drug-Eluting Stent
HTA	Health Technology Assessment
ICD	International Classification of Diseases
INAHTA	International Network of Agencies for Health Technology Assessment
ISR	In-Stent Restenosis
MUHC	McGill University Health Centre
NICE	National Institute for Clinical Excellence
OR	Odds Ratio
PCI	Percutaneous Coronary Intervention
PTCA	Percutaneous Transluminal Coronary Angioplasty
QALY	Quality Adjusted Life-Years
RAMQ	*Régie de l'assurance maladie du Québec*
RQCT	*Réseau québécois de cardiologie tertiaire*
RR	Relative Risk
RSR	Restenosis Rates
RVH	Royal Victoria Hospital (McGill University Health Centre)
TAU	Technology Assessment Unit, McGill University Health Centre

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