

# The practice of percutaneous coronary interventions in hospitals without on-site cardiac surgery: review of guidelines and analysis of Quebec data, 1999-2004

Summary

Information brief

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





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## INFORMATION BRIEF

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*An information brief is an assessment presenting the main findings of a rigorous analysis of the scientific literature, supplemented, if necessary, with an examination of clearly defined contextual issues. An information brief is based on a targeted literature search, the gathering of relevant contextual information and, sometimes, consultations with experts. This type of document is usually not examined by external reviewers but is submitted to the members of AETMIS's Board for their information or approval.*

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# PREFACE



**P**ercutaneous transluminal coronary angioplasty, or percutaneous coronary intervention (PCI), is a technique for percutaneously opening up or dilating coronary arteries narrowed or occluded by lesions. It is generally performed in catheterization laboratories at hospitals that have cardiac surgery to deal with the serious complications that can occur. However, these complications are rare, and in the past several years PCI has also become available at hospitals without such surgical support in many parts of the world. Despite the advantages of this practice, especially in terms of patient access, its advisability and safety are still being debated.

The Conseil d'évaluation des technologies de la santé (CETS), which became AETMIS in June 2000, had examined this matter twice, in 1989 and 1997, and published reports that pointed to the gradual improvement in the safety of PCI. While the first report concluded that on-site surgical backup was necessary, the more recent report opened the door to off-site surgical support, provided certain criteria were met concerning patient selection, procedures and times for patient transfer, the intervention teams and monitoring of outcomes. Consequently, over time, five PCI centres without on-site surgery have been set up in Québec, although a cautionary approach has been maintained.

However, the Ministère de la Santé et des Services sociaux (MSSS) continues to receive requests for opening catheterization laboratories without on-site surgical support in areas with varying distances from major urban centres and from the nearest cardiac surgery facility. It was in this context that the MSSS commissioned AETMIS to address the following question:

*To what extent is the Ministry justified in maintaining the position according to which the development of diagnostic and therapeutic catheterization should be reserved for centres with on-site surgical support or centres within an hour's reach of a centre with cardiac surgery?*

To address this question, this study presents a review of the latest relevant guidelines, an examination of the available evidence, and an analysis of Québec data. This analysis uses medico-administrative data to compare the outcomes of PCI performed in Québec hospitals with and without on-site cardiac surgery.

Juan Roberto Iglesias, M.D., M.Sc.  
President and Chief Executive Officer

# EXECUTIVE SUMMARY

**P**ercutaneous coronary intervention (PCI) is a technique for opening up or dilating coronary arteries narrowed or occluded by atherothrombotic lesions. It is generally performed in catheterization laboratories in hospitals that have on-site cardiac surgery to deal with certain serious, albeit rare, complications that can occur. However, over the past several years, there have been pressures worldwide to perform PCI at facilities without on-site cardiac surgical support. Québec already has five such centres (more than in the rest of Canada combined), but the Ministère de la Santé et des Services sociaux (MSSS) continues to receive requests for opening new catheterization laboratories in hospitals without on-site cardiac surgery. Despite the advantages of this practice in terms of patient access, its advisability and safety are still being debated.

It was in this context that the MSSS asked AETMIS to examine these issues. The present assessment is based on a review of the most recent guidelines that exist in other jurisdictions, and on an analysis of Québec medico-administrative data for PCIs performed from 1999 to 2004.

The recommendations and guidelines for the practice of PCI at centres without on-site surgery vary considerably. Certain professional organizations advise against performing PCI at such centres, except in patients with ST-elevation myocardial infarction (STEMI). Others recommend that centres without on-site surgery should only treat patients at low risk for complications. In general, the guidelines urge caution in creating PCI centres without on-site surgical support and stress the need for mentorship by established tertiary cardiology centres, for high institutional and operator volume, for clear protocols for rapid patient transfer when emergency cardiac surgery is required, and for continuous clinical outcome monitoring.

A review of the available evidence indicates that clinical outcomes are slightly but significantly less favourable in patients who undergo PCI at centres without on-site cardiac surgery, even in highly controlled conditions with rigorous selection of low-risk patients. The same observation emerges from the analysis of PCI outcomes in Québec, using a first PCI as the index event. Although these results should be considered preliminary because of the limitations of the analysis, the 1-year overall mortality risk appears to be significantly higher at centres without on-site cardiac surgery. The relative and absolute increases in this risk are estimated at 29% and 1.4%, respectively, compared to the risk observed in centres with on-site cardiac surgery.

Although the opening of PCI centres without on-site surgery might be considered in order to be able to offer primary PCI more widely in Québec to patients with STEMI and to treat them more rapidly, this rationale is tempered by two factors. One is that primary PCI accounts for less than one fourth of all PCIs. The other is that fibrinolytic therapy is a well-accepted alternative for treating patients with STEMI throughout Québec that is readily available in any healthcare centre equipped with an emergency room.

This report highlights the persistent uncertainty regarding the real advantages of the practice of PCI in centres without on-site surgery and leads AETMIS to advise caution in response to the continuing demand for the expansion of such centres. In all cases, given the considerable resources required to perform PCI and achieve its benefits, and the inherent risks associated with invasive interventions, this assessment emphasizes the importance of interhospital collaboration, the establishment of clear protocols, and commitment to essential quality-of-care conditions. The report also stresses the need for a high-quality data registry, and the monitoring of performance, all essential to ensure the most favourable patients outcomes and optimal allocation of resources.

# SUMMARY

## Introduction

Percutaneous transluminal coronary angioplasty, or percutaneous coronary intervention (PCI), is a technique for opening up or dilating coronary arteries narrowed or occluded by atherothrombotic lesions. It involves sliding a catheter to the lesion site and mechanically improving or restoring circulation, using an inflatable balloon. Very often, one or more stents are inserted into the dilated arteries. PCI is generally performed in catheterization laboratories at hospitals that have cardiac surgery available to deal with the serious complications that can occur. However, these complications are rare, and over the past several years, there have been pressures worldwide to perform PCI at hospitals without such surgical support.

In 1999, in Québec, four hospitals without such on-site surgical support had been authorized by the Ministère de la Santé et des Services sociaux (MSSS) to perform PCI, but the MSSS frequently receives new requests. A fifth PCI centre without on-site cardiac surgery was opened in 2007. Presently, the number of PCI centres without on-site cardiac surgery in Québec is greater than the total number of such centres in the rest of Canada. To help in its decision making, the MSSS asked the AETMIS Tertiary Cardiology Evaluation Unit to prepare a review of the pertinent guidelines and to analyze the outcomes of PCI performed in existing centres in Québec.

## Clinical settings

PCI can be performed in a wide variety of clinical settings. Primary PCI is an initial reperfusion therapy for ST-segment elevation myocardial infarction (STEMI). During STEMI, damage to myocardial tissue becomes more extensive from minute to minute. Minimizing the time between the onset of symptoms and the opening up of the coronary artery is, in fact, a critical factor for optimizing the patient's outcomes. This is why primary PCI is performed with utmost urgency in these patients. However, the vast majority of PCIs are used to treat other clinical entities, such as stable and unstable angina and myocardial infarction without ST-segment elevation (NSTEMI), with varying levels of urgency and priority. For these cases, the benefits of PCI are not strictly time-dependent as is the case for primary PCI, and the transfer of a patient in need of coronary angiography and possibly PCI to a PCI facility with on-site cardiac surgery that may be further away than a PCI facility without on-site surgery does not entail greater risk.

## The practice at percutaneous coronary intervention (PCI) centres without on-site cardiac surgery

The first PCI centres without on-site surgery were set up to facilitate and improve access to elective PCI. Many patients were able to take advantage of their greater proximity to this service and not have to travel to a hospital with cardiac surgery. However, arguments against this practice have been raised. First, it is difficult to predict which patients are likely to experience complications requiring emergency cardiac surgery. Second, if greater time to treatment does not have a harmful effect, it would be to the patient's advantage to be treated at a centre that does have cardiac surgery, where the volume of

interventions and the level of competence and experience are likely to be higher and where the support services can more easily deal with any complication.

In Québec, access to elective or not extremely urgent PCI is generally not a problem, since the existing centres are usually able to meet patient needs in a timely fashion. However, there is a question about their ability to adequately treat patients with STEMI, across Québec, who require access to reperfusion in a very short period of time. Yet, in this case, fibrinolysis is a well-accepted alternative for treating STEMI. This is a pharmacologic treatment designed to dissolve the clot responsible for the coronary occlusion. If there are no contraindications, fibrinolysis can be administered in any hospital or other healthcare facility emergency room or even, in certain regions outside Québec, by qualified prehospital emergency services personnel. In fact, a very recent AETMIS assessment shows that the difference in efficacy between primary PCI and fibrinolysis is relatively small in the short term (30 days) and depends on the delay to treatment and the level of competence and experience of the personnel. If the outcomes of primary PCI performed at centres without on-site cardiac surgery are at all unfavourable, they would cancel out the slight advantage of these interventions over fibrinolysis. In the longer term, no statistically significant difference in the efficacy of primary PCI and fibrinolysis has yet been demonstrated.

## Guidelines

The recommendations and guidelines for PCI practice at centres without on-site surgery vary widely. The most recent guidelines (2005) were published in the United States by a joint committee consisting of members of the American College of Cardiology (ACC), the American Heart Association (AHA) and the Society for Cardiovascular Angiography and Interventions (SCAI). The guidelines state that **elective PCI** should not be performed at hospitals without on-site cardiac surgery. However, they indicate that **primary PCI** might be considered for patients with STEMI at hospitals without on-site surgery, provided the appropriate operational procedures are in place and are applied.

Although the guidelines of the European Society of Cardiology (ESC) touch on the subject of PCI only very briefly, highlighting the efficacy and safety of primary PCI performed in high-risk patients at hospitals without on-site surgery, different countries in the European Union were found to have more specific recommendations. While they varied as to whether or not on-site surgical support is required, they all emphasized that certain operating conditions needed to be in place to perform PCI safely. This view is also expressed in the Australian, New Zealand and Ontario guidelines.

As clearly stated by the British Cardiac Society (BCS) and the British Cardiovascular Intervention Society (BCIS), provision for emergency cardiac surgery is an essential prerequisite. They specify that in the case of major complications, the time from the medical decision to transfer the patient to a facility with cardiac surgery to the time when extracorporeal circulation is established must not exceed 90 minutes. This requirement is already quite difficult to meet in a hospital with on-site cardiac surgery and is thus even more difficult to meet when an interhospital transfer is necessary. Other guidelines also propose maximum delays but they are defined in different ways and assume the existence of official protocols stipulating all the necessary steps for immediate and effective patient transfer.

Some of the other measures usually required of a PCI centre without on-site surgery are mentorship by an established tertiary cardiology centre, high annual institutional and operator volumes, the availability of well-trained personnel and suitable equipment, continuous clinical outcome monitoring and, in certain cases, appropriate patient selection criteria.

## Analysis of Québec data: methods

The second part of this information brief describes the methods and results of the analysis by AETMIS of medico-administrative data for hospitals that offer PCI services. The outcomes of a first PCI performed at hospitals without on-site surgery ( $n = 4$ ) were compared with the outcomes of a first PCI performed at hospitals with on-site surgery ( $n = 11$ ). Only the first PCI undergone by the patient was selected in order to minimize confounding factors. It should be emphasized that the medico-administrative databases cannot presently distinguish between primary PCI and PCI for other indications. Two time periods were used in the comparison: 1999 to 2001 and 2002 to 2004. The outcome measures evaluated included the rates of 30-day and 1-year mortality and the rate of coronary artery bypass graft operations (CABGs) performed within one day of PCI. The latter was considered to be an indicator of the need for emergency cardiac surgery following a complicated PCI.

The data were obtained from multiple sources and required linkage, by an encrypted patient identifier, that was performed with the assistance of the relevant administrative bodies and in accordance with confidentiality requirements. Data identifying PCI and CABG were obtained from the fee-for-service file of the Régie de l'assurance maladie du Québec (RAMQ) and mortality data from the Québec death registry (Institut de la statistique du Québec). The comorbidities of interest were determined using the Québec hospital morbidity database (Med-Écho) by examination of the main and secondary diagnoses for hospitalizations within the five years preceding the first PCI as well as for the PCI-related hospitalizations.

## Results of the analysis

*From 1999 to 2001*, after adjustment for age group and gender, the rate of emergency CABG surgery (at one day following a first PCI) was more than 5-fold lower (OR = 0.17; 95% CI: 0.05-0.54) at the hospitals without on-site cardiac surgery (absolute values: 0.08% vs. 0.46%). The risk of 30-day mortality was 2.50% for PCI performed at hospitals without on-site cardiac surgery and 2.60% at those with on-site surgery, with no significant difference after adjustment for age group, gender and comorbidities (OR = 0.92; 95% CI: 0.71-1.19). One year after a first PCI, 5.16% of the patients treated at hospitals without on-site surgery had died compared to 5.22% of those treated at hospitals with surgical services. After adjusting for age group, gender and comorbidities, there was no difference in risk of death at one year (OR = 0.98; 95% CI: 0.82-1.17) between the two types of hospitals.

However, *from 2002 to 2004*, the 30-day mortality rate increased to 3.08% in hospitals without on-site cardiac surgery while it decreased very slightly to 2.40% at hospitals with surgery. During this more recent period, after adjustment for age group, gender and comorbidities, a first PCI performed at a hospital without on-site surgery was associated with a 31% increase in risk of death at 30 days (OR = 1.31; 95% CI: 1.08-1.59) compared to the risk in hospitals with on-site surgery. The excess risk of death persisted

to one year after PCI. The 1-year mortality rate for hospitals without surgery increased to 6.53% (it was 5.16% during the previous period,  $p = 0.01$ ), while it decreased very slightly for facilities with surgery, from 5.22% to 5.13% ( $p = 0.71$ ). After adjustment for age group, gender and comorbidities, the risk of death during the year following PCI was 29% higher (OR = 1.29; 95% CI: 1.10-1.51) for hospitals without on-site cardiac surgery than for those with surgery. The observed increase in risk associated with performance of PCI in hospitals without on-site surgery is not inconsistent with existing evidence in the literature.

During 2002 to 2004, the rate of emergency CABG surgery (at one day following a first PCI) remained very low (0.09%) at hospitals that did not have on-site cardiac surgery. In surgical centres the rate of emergency CABG decreased from 0.46% during 1999-2001 to 0.35% during 2002-2004. After adjustment for age group and gender, the emergency CABG rate was 4-fold lower (OR = 0.24; 95% CI: 0.10-0.59) in hospitals without surgery compared to those with surgery.

During both periods, the prevalence of comorbidities was very similar in the two types of hospitals. Although almost all were included in the final model, these comorbidities had little influence on the estimates of the age- and gender-adjusted relative risk. During the more recent period, however, the patients at both types of hospitals were more likely to be 80 years of age or older, to be diabetic and to have been diagnosed with acute myocardial infarction on admission for PCI. Therefore, Québec's hospitals seem to have followed the general trend observed elsewhere of performing more complex and more difficult PCI in patients with more morbidity, all factors that are associated with greater risk.

## Limitations of the analysis

The results of this analysis should be considered preliminary because of the numerous limitations of the immediately available data. For instance, only the first PCI performed in a patient was included in the analysis. It was not possible to distinguish between an emergency PCI and a PCI performed in a patient with a more stable clinical status, to identify PCI performed to treat STEMI or to consider important characteristics of the coronary lesions (complex lesions, multivessel disease). Furthermore, the comparative picture would be more complete if diagnostic coronary angiography had also served as an index event for examining mortality and rate of emergency CABG at hospitals with and without on-site cardiac surgery. Consequently, the conclusions drawn from these results should be interpreted with caution until more thorough analyses of more recent data can be performed.

## Conclusion

In clinical medicine, as in other areas, demand tends to be a function of available supply. The creation of new PCI centres would, therefore, probably lead to the increased use of coronary angiography and PCI. Given the lack of evidence showing an improvement in survival associated with PCI being performed more quickly in most clinical settings, and given the risks associated with performing PCIs at facilities without on-site cardiac surgery, the real advantages of creating new PCI centres without surgical support are uncertain.

Consequently, based on a review of the latest guidelines, available evidence and a preliminary analysis of outcomes of PCI in Québec, this information brief underlines the need for caution in the creation, expansion and operation of PCI centres without on-site cardiac surgery. Given the considerable resources required to perform PCI and achieve its benefits, and the inherent risks associated with invasive interventions, this assessment emphasizes the importance of interhospital collaboration, the establishment of clear protocols, commitment to essential quality-of-care conditions, the need for a high-quality data registry, and the monitoring of performance, all measures essential to ensure the most favourable patient outcomes and optimal resource allocation.

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