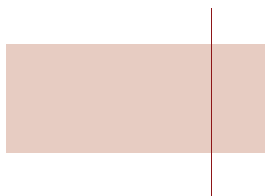


Organizational and Economic Issues in the Management of Patients with Acute ST-segment Elevation Myocardial Infarction (STEMI)

Summary

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



Organizational and Economic Issues in the Management of Patients with Acute ST-segment Elevation Myocardial Infarction (STEMI)

Summary

Report prepared for AETMIS by

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February 2008

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MISSION

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PREFACE



Approximately 4800 patients in Quebec are hospitalized annually with a diagnosis of myocardial infarction with ST-segment elevation (STEMI). STEMI is a serious acute condition in which the immediate cause is the occlusion of a coronary artery by a thrombus. The typical presenting symptom is retrosternal chest pain. In the absence of an intervention in the hours following this occlusion, the area of the cardiac muscle (myocardium) normally irrigated by this artery will suffer irreversible damage of some degree (infarction). The more rapid the intervention, the greater the proportion of myocardium saved, the less extensive the infarction and the better the prognosis. There are two methods to reopen the coronary artery responsible for a STEMI and reperfuse the jeopardized myocardium, fibrinolysis and percutaneous coronary intervention (PCI). Both of these are recommended in the clinical practice guidelines of North American and European cardiac professional societies.

Fibrinolysis refers to the intravenous administration of a medication to dissolve the thrombus that is obstructing the coronary artery. In Quebec, the fibrinolytic agent is generally administered in the emergency room under the surveillance of a physician. Certain patients have contraindications to fibrinolysis such as an elevated risk of bleeding, and PCI is thus the more appropriate treatment in general for such patients. Others may require PCI if fibrinolysis is unsuccessful. Primary PCI (PPCI) is a mechanical intervention that reopens the obstructed coronary artery with a balloon and one or more stents are generally inserted to stabilize the reopened artery. PCI is performed in a specialized hospital with a catheterization laboratory by an experienced interventional cardiologist with the assistance of qualified nurses and technical staff.

Time is the most critical factor to save the myocardium at risk and to improve prognosis of patients suffering from STEMI. Existing evidence and clinical practice guidelines emphasize the importance of minimizing the delay to reperfusion for such patients and the latter make specific recommendations of permissible time frames for treatment.

This clinical context led the Minister of Health and Social Services (MSSS) to initiate a cardiology program in December 2005 with the objective of improving the continuum of urgent care, particularly for patients suffering from STEMI. The Minister also requested that the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) shed light on the scientific, organizational and contextual issues concerning the optimal management of these patients. In response to this request, the present report considers pertinent existing evidence and clinical practice guidelines and examines approaches to reduce treatment delays at different points in the clinical pathway of STEMI patients, including the use of prehospital ECGs as well as the measurement of performance and quality of care necessary to ensure the efficient administration of treatments, while considering the issues relative to resources and costs specific to the Quebec context.

Juan Robert Iglesias, MD, MSc,
President and Chief Executive Officer



EXECUTIVE SUMMARY

In Quebec, it is estimated that 4800 patients are hospitalized each year for acute myocardial infarction with ST-segment elevation (STEMI). The immediate cause of this serious condition is the occlusion of a coronary artery by a thrombus that must be urgently cleared to minimize irreversible damage to the cardiac muscle. There are two treatments that can be used to reopen the occluded artery, fibrinolysis and primary percutaneous coronary intervention (PPCI). Both treatments are recommended in clinical practice guidelines of different countries. According to these guidelines and available evidence, it cannot be affirmed that one of these methods of reperfusion is superior to the other for all patients in all clinical situations, at all times of the day. In this context, the best treatment for a particular patient will be that which is clinically appropriate and administered in a timely fashion, that is, within recommended delays. Such management is dependant on optimal organization and delivery of care and services.

The present evaluation report, prepared at the request of the Ministry of Health and Social Services, examines the applicability of existing evidence and clinical guidelines for Quebec, by considering the current context of care and related issues with respect to organization and resources, and describes approaches that can reduce delays to treatment.

In light of this evaluation, AETMIS recommends:

- 1) that fibrinolysis and PPCI be recognized as complementary modes of intervention where the choice of treatment depends on a variety of clinical and practical considerations;
- 2) that treatment delays be minimized for both therapies, at each point of care from emergency medical services (with regards to any initial care or interhospital transfer) to the initial receiving hospital and to PPCI hospitals that may receive patients for PPCI;
- 3) that recourse to PPCI not be the preferred option when the expected door-to-balloon time exceeds the delay recommended in clinical practice guidelines, and that the initial decision to proceed to fibrinolysis or PPCI (when such a choice is possible) be based on an evaluation of the individual patient's risk profile and the anticipated delays to both treatments;
- 4) that performance monitoring of prehospital ECG initiatives be implemented at the local, regional, and provincial level;
- 5) that the implementation of pilot projects for the administration of prehospital fibrinolysis be considered, particularly in remote regions, as a strategy to markedly reduce delays to reperfusion treatment in STEMI;
- 6) that interested and concerned organizations establish protocols of understanding and encourage discussion between the diverse participants in STEMI care and collaboration between hospitals and ambulance services;
- 7) that training in emergency medicine and cardiology include theoretical and practical education on both modes of reperfusion for STEMI;
- 8) that performance (especially timeliness of reperfusion treatment) be monitored at the provincial level across the continuum of care — in the prehospital phase, in the emergency room, in the catheterization laboratory, and particularly in the case of interhospital transfer — and that regular, timely feedback be provided to all caregivers involved;
- 9) that incentives be introduced to facilitate and reinforce appropriate use of fibrinolysis and PPCI by health professionals and institutions.

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None to be declared.

SUMMARY

Introduction

The issue

It is estimated by the Quebec tertiary cardiology network (RQCT) that 30% of acute myocardial infarctions are characterized by ST-segment elevation on an ECG, representing approximately 4800 patients hospitalized annually in Quebec. This type of acute myocardial infarction, hereafter referred to as STEMI, is a serious condition in which the immediate cause is the occlusion of a coronary artery by a thrombus. In the absence of an intervention in the hours following this occlusion, the area of the myocardium normally irrigated by this artery will suffer irreversible damage to some degree. The more rapid the intervention, the greater the proportion of myocardium saved, the less extensive the infarction and the better the prognosis. There are two well-established and recognized methods to reopen the coronary artery responsible for the STEMI and reperfuse the jeopardized myocardium, fibrinolysis and percutaneous coronary intervention (PCI).

Fibrinolysis refers to the intravenous administration of a medication to dissolve the thrombus that is obstructing the coronary artery. In Quebec, the fibrinolytic agent is generally administered in the emergency room under the surveillance of a physician. Certain patients have contraindications to fibrinolysis such as an elevated risk of bleeding, and PCI is thus the more appropriate treatment in general for such patients. Others may require PCI if fibrinolysis is unsuccessful. Primary PCI (PPCI) is a mechanical intervention that reopens the obstructed coronary artery with a balloon, generally with the insertion of one or more stents to better stabilize the artery. PCI is performed in a catheterization laboratory in a specialized hospital by an experienced interventional cardiologist with the assistance of qualified nurses and technical staff.

Time is the critical factor to improve the prognosis of patients who suffer from STEMI. Existing evidence and clinical practice guidelines emphasize the importance of minimizing the delay to reperfusion for these patients and the latter make specific recommendations of permissible time frames for treatment.

The request for an evaluation from MSSS

This context led the Minister of Health and Social Services (MSSS) to initiate a cardiology program in December 2005 with the objective of improving the continuum of urgent care, particularly for patients suffering from STEMI. The Minister also requested that the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) shed light on the scientific, organizational and contextual issues concerning the optimal management of these patients. In response to this request, the present report considers pertinent existing evidence and clinical practice guidelines and examines approaches to reduce treatment delays at different points in the clinical pathway of STEMI patients, as well as the measures of performance and quality of care necessary to ensure efficient administration of treatment, while considering the issues relative to resources and costs in the Quebec context.

Choice of treatments and delays to administration: existing evidence and clinical guidelines

In their clinical practice guidelines, North American and European cardiology societies clearly recognize both fibrinolysis and PPCI as methods of reperfusion for the treatment of STEMI. These clinical guidelines stipulate that the delay to administration of fibrinolysis after hospital arrival must not exceed 30 minutes and according to the Canadian guidelines, should ideally be 15 to 20 minutes. For PPCI, the delay between the arrival of the patient at a hospital and balloon inflation should not exceed 90 minutes (60 minutes, according to European guidelines, when reperfusion is clearly indicated) and, according to the Canadian guidelines, the delay should ideally be 40-60 minutes. Current North American guidelines emphasize that neither reperfusion treatment is systematically preferred for all patients in all circumstances, and that timely reperfusion is likely more important than choice of which treatment. A systematic review conducted at the request of AETMIS shows that differences in safety and efficacy between the two treatments are relatively modest in absolute terms and depend on factors such as treatment delay, expertise of the intervention team, and patient clinical characteristics. The results of the randomized trials, which were carried out in ideal or well-controlled conditions, are based on a 40-minute mean difference between the performance of PPCI in centres of excellence and the administration of fibrinolysis. It is for this reason that American and Canadian guidelines recommend that the additional delay necessary to perform PPCI be less than 60 minutes from what would be the time of immediate administration of fibrinolysis.

Fibrinolysis is generally available in any emergency room and, in some cases outside Quebec, during the prehospital phase. PPCI in comparison is a “tertiary” cardiac treatment that requires specialized facilities; its use therefore poses larger logistic and organizational challenges. The present report recognizes the particular importance of PPCI for STEMI patients who are at high risk or for whom fibrinolysis is contraindicated. Nevertheless, and considering the crucial importance of time, a key question for decision-makers is: how much system organization and resources should be allocated to continue to increase availability for PPCI for most patients to the exclusion of a second viable option, fibrinolysis, that is currently readily available at the first point of care?

Both approaches to reperfusion are continuously evolving and the future is likely to see changes and improvements in treatment, whose direction and nature are presently unpredictable. This dynamic should incite caution in instituting complex and expensive infrastructural changes that may be overtaken by novel discoveries and developments.

Finally, it is important to consider that in Canada, the United States and Europe, an important proportion of patients who suffer STEMI (about one third) receive no reperfusion treatment. As this group presents the worst prognosis, any improvement in their treatment could result in major clinical benefits.

Current situation in Québec

In present-day Québec, PPCI has become the preferred and predominant treatment option, for over half of all STEMI patients who receive reperfusion therapy, and very few patients who present to a hospital with PCI facilities receive fibrinolysis. This contrasts with other jurisdictions examined in the present report (Canada, USA, Europe), where about 40% of STEMI patients presenting at PCI centres receive fibrinolysis. In Quebec, hospitals that do not offer PCI and are within a radius of about 60-100 km of PCI centres

generally choose to transfer their patients to undergo this intervention. However, the results of the AMI-QUEBEC study, that are consistent with other data from Quebec and elsewhere, indicate that less than 10% of patients transferred for PPCI have “door-to-balloon” times within the recommended guidelines. When the interhospital transport time exceeds 30 minutes, it is unlikely that a STEMI patient can receive PPCI within the recommended delays.

The growing use of PPCI creates pressures within the healthcare system to open new PCI centres and expand existing facilities to increase access to PPCI, and to increase emergency services and ambulance resources, already in demand for other medical and social needs, to ensure efficient transport of STEMI patients. Other factors may modulate this dynamic. The current marked recourse to PPCI and the increasing use of direct transfers to catheterization laboratories has the effect of making clinicians and physicians in training increasingly unfamiliar and insecure with the prospect of administering fibrinolytic therapy. Contrary to the case of PPCI, the administration of fibrinolytic therapy is not a specifically remunerated medical act (as elsewhere in Canada, although there are other inter-provincial differences in payment mechanisms in general). When fibrinolysis is administered in the emergency department, the patient must be closely monitored for a certain time and a decision may be subsequently made to transfer for PCI. Often this is in a context where the clinician’s time is already being solicited by other patients in the emergency room. With all of these considerations in mind, the pressure to expeditiously transfer the patient out of the emergency department to a PCI centre (which is itself “competing” with other specialized sites to maintain sufficient PPCI volume and expertise) can be considerable.

Canadian guidelines recommend that the decision to opt for PPCI should be made on the basis of an individual evaluation of risk in order to direct the patients who are the most at risk to PCI centres, which must also treat a patient clientele in stable or unstable conditions on an elective or urgent basis. In reality, catheterization laboratories are occupied most of the time during normal working hours for planned interventions. The increased initial recourse to tertiary cardiac services for a growing proportion of patients creates and will create more and more pressure on scarce ambulance resources already in demand for other medical and social needs.

The prehospital phase of care

Prehospital ECG strategies are likely to become increasingly important in Quebec in the coming years. The evidence from the literature suggests that these strategies can be valuable for reducing delays to reperfusion, as long as certain feasibility issues are addressed and programs are implemented in a manner that integrates emergency medical services (EMS) and hospital processes. These programs require a significant investment in terms of organization and resources. These strategies have the potential to assure more timely PPCI (through prehospital diversion of STEMI patients directly to PCI centres or more rapid decision and turnaround time at the first hospital door in the case of transfers) or more timely fibrinolysis (through prehospital administration of fibrinolytic agents or more rapid in-hospital administration).

Quebec’s EMS structure, however, which currently relies on ambulance personnel trained only in basic life support implies that: 1) innovative solutions are needed for the interpretation of ECG findings (e.g. by computer programs and/or designated remote physicians, for example); 2) prehospital diversion programs to PCI centres need to carefully consider how to safely extend patient transport times; and 3) programs incorporating more advanced processes for ambulance personnel (notably ECG

interpretation and prehospital fibrinolysis) will need a long-term plan to develop advanced life support (ALS) capability more widely in the province. With regards to prehospital diversion to PCI centres, organizational challenges and long-term effects on the maintenance of expertise in STEMI management in emergency departments in general also need to be considered. Remote regions where transport to hospital is prolonged offer an interesting opportunity to implement prehospital fibrinolysis programs.

Reduction of delays: organizational themes

The principal organizational themes arising from our analysis of approaches to reduce delays to reperfusion are the following:

Protocols. Within a health institution and within networks (such as those involving EMS and hospitals), protocols that are workable and clear and adapted to local circumstances are necessary to specify the roles and responsibilities of each health care provider and the processes of care to be followed. Protocols clarify who should be making the decision about which reperfusion treatment should be offered to the patient in highlighting the key role of the emergency physician at the first point of care. In all cases, when both reperfusion options are available, the choice of treatment, according to results of randomized trials and clinical guidelines, should ensure that there is a delay of less than 60 minutes (and ideally 40 minutes) between the immediate administration of fibrinolysis and the reasonably anticipated time to PPCI. It is essential that these protocols be the result of a broad participatory process where the ideas, expertise, and interests of all parties implicated (e.g. cardiologists, emergency room physicians, hospital and regional administrators, ambulance personnel and dispatchers) be considered.

Networks. Integration of services and communication between health care providers at different levels and between organizations are necessary to ensure collaboration between health professionals, in-hospital services, institutions and EMS. The development of new strategies and procedures requires the consultation and participation of all participants in the continuum of care.

Patient-centred care. Consideration of the individual patient's needs and circumstances is necessary to provide care that adheres as much as possible to clinical guidelines and ethical norms. Where two timely reperfusion treatment options are available, there is a true choice for the patient without contraindications. Otherwise, in accordance with current clinical practice guidelines, it seems preferable for the majority of patients to ensure that timely fibrinolysis (if appropriate) is not denied in favour of untimely PPCI.

Performance monitoring. Performance and progress over time can only be fully measured and analyzed through the centralized, systematic and continuous monitoring of processes of care and patient outcomes for all of Quebec. The United Kingdom has shown the tremendous impact of performance monitoring and wide dissemination of quality indicators on improving care and outcomes for patients with STEMI. In Quebec, such monitoring would enable the measurement of the impact of changes to organization of care and new strategies. It is essential that all strategies of performance monitoring provide regular and timely feedback to all caregivers in each region to support and stimulate a dynamic process of quality improvement in care and provision of services.

Economic Issues

Several questions of economic investment have been raised in this report. These include the importance for Quebec policy-makers to consider the resources required for:

- ensuring ongoing monitoring of use of reperfusion therapies and their timeliness, for which clear identification of STEMI patients is necessary in medico-administrative databases;
- implementing prehospital ECG programs, notably with respect to purchasing of equipment that may become out-dated as technologies develop and improve;
- development of ALS training, as a long-term goal, if paramedic recognition of STEMI, extended ambulance transport or prehospital fibrinolysis are considered important for the future.

Conclusions

At the time of writing of this report, the available evidence suggests that, for the majority of patients, the relative advantage of PPCI is likely to be modest and is conditional on optimal treatment delivery. The systematic recourse to PPCI when time from arrival at the first hospital door to balloon inflation will realistically exceed current guideline recommendations is unsupported by an analysis of randomized controlled trials. When interhospital transport time for PPCI exceeds 30 minutes, it is rare that STEMI patients can be treated within recommended guidelines.

In Quebec, as in other jurisdictions, PPCI is not available to all patients presenting with STEMI because expert facilities with sufficient volume simply cannot be established in all geographic regions. And indeed, in the case of STEMI patients without high risk features and without contraindications, fibrinolysis is a viable reperfusion option with recognized efficacy. When a choice is possible, the initial decision to proceed with fibrinolysis or PPCI should be based on an evaluation of the risk profile of each patient and the expected delays to treatment, particularly the time to immediate fibrinolysis, the anticipated time to dilatation by balloon and the difference between these two delays.

In the specific case of Quebec, where enormous PCI expertise exists but PPCI treatment times generally appear to exceed recommended norms, it appears necessary, as a first step, to improve performance and reconsider how best to provide timely PPCI for those patients who need it most. An initial strategy of quality improvement, through a variety of prehospital, intrahospital and interhospital changes, and that targets high risk and fibrinolysis-ineligible patients appears to be an appropriate starting point.

To improve the quality of STEMI care, hospitals should be encouraged to develop their own innovative strategies to streamline care pathways for STEMI patients, both within their facilities and in collaboration with EMS. Non-PCI hospitals should be provided with the necessary support to speed up ECG administration, improve the interpretation of ECGs, and facilitate the timely administration of fibrinolysis, post-fibrinolysis monitoring, and decision-making about the necessity for follow-up tertiary care. Inter-disciplinary communication and collaboration should be fostered between care providers in the different settings (EMS, emergency department, specialist care), and with bodies involved in performance monitoring. Incentives and disincentives to promote evidence-based care and respect of practice guidelines, as well as to facilitate performance monitoring, could also be considered.

Given current interests in prehospital ECG programs, there is a window of opportunity to ensure that their feasibility, safety, resource needs, long-term implications and overall vision are considered. Consultation with representatives of all stakeholders from EMS, non-PCI hospitals and PCI sites, among others, should be integral to initiatives, as well as the sharing of experiences between regions. Finally, in the framework of a global strategy for management of STEMI, a province-wide system of performance monitoring should be established to enable tracking of treatment times and to encourage local and regional initiatives (involving local facilities and EMS as well as regional health and social service agencies) and to monitor the impact of changes in structures or processes of care. Such an approach would be facilitated by the prior establishment of performance norms at the provincial level.

Recommendations

In light of this evaluation, AETMIS recommends:

- 1) that fibrinolysis and PPCI be recognized as complementary modes of intervention where the choice of treatment depends on a variety of clinical and practical considerations;
- 2) that treatment delays be minimized for both therapies, at each point of care from emergency medical services (with regards to any initial care or interhospital transfer) to the initial receiving hospital and to PCI hospitals that may receive patients for PPCI;
- 3) that recourse to PPCI not be the preferred option when the expected door-to-balloon time exceeds the delay recommended in clinical practice guidelines, and that the initial decision to proceed to fibrinolysis or PPCI (when such a choice is possible) be based on an evaluation of the individual patient's risk profile and the anticipated delays to both treatments;
- 4) that performance monitoring of prehospital ECG initiatives be implemented at the local, regional, and provincial level;
- 5) that the implementation of pilot projects for the administration of prehospital fibrinolysis be considered, particularly in remote regions, as a strategy to markedly reduce delays to reperfusion treatment in STEMI;
- 6) that interested and concerned organizations establish protocols of understanding and encourage discussion between the diverse participants in STEMI care and collaboration between hospitals and ambulance services;
- 7) that training in emergency medicine and cardiology include theoretical and practical education on both modes of reperfusion for STEMI;
- 8) that performance (especially timeliness of reperfusion treatment) be monitored at the provincial level across the continuum of care — in the prehospital phase, in the emergency room, in the catheterization laboratory, and particularly in the case of interhospital transfer — and that regular, timely feedback be provided to all caregivers involved;
- 9) that incentives be introduced to facilitate and reinforce appropriate use of fibrinolysis and PPCI by health professionals and institutions.

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