Canadian quality indicators for percutaneous coronary interventions

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DT Ko, HC Wijeysundera, X Zhu, J Richards, JV Tu; and the National Expert Panel. Canadian quality indicators for percutaneous coronary interventions. Can J Cardiol 2008;24(12):899-903.

BACKGROUND: Quantifying adherence to quality indicators can serve as a direct measure of quality of care and provide the foundation for quality improvement. However, quality indicators for percutaneous coronary intervention (PCI) have not been developed in Canada.
OBJECTIVE: To develop a set of quality and outcome indicators for PCI that can be used across Canada.
METHODS: A 12-member national expert panel was selected to represent practice in different regions of Canada. Potential quality indicators were identified by a detailed search of published guidelines, randomized trials and outcomes studies. A two-step modified Delphi process was employed with an initial screening round of indicator ratings, followed by a national quality indicator panel meeting, and follow-up discussions to obtain consensus.
RESULTS: A total of 26 indicators including six structure indicators, nine process indicators, and 11 outcomes indicators were identified by the national expert panel to be representative of high quality of care for PCI. Pharmacological indicators included prescription of acetylsalicylic acid, clopidogrel and statin therapy as adjunctive therapy for PCI. Nonpharmacological process indicators included minimal procedure volumes, door-to-balloon time in primary PCI, prevention of contrast-induced nephropathy and selected patient education counselling instructions. Outcome indicators included death, myocardial infarction, target vessel revascularization and vascular access complications after PCI.
CONCLUSIONS: A new set of PCI quality indicators for use in the Canadian health care system was developed. The widespread adoption and implementation of PCI quality indicators in clinical practice will facilitate the identification of practice gaps to enable quality improvement efforts and to optimize the outcomes of patients undergoing PCI throughout Canada.

Key Words: *Delphi panel; Outcome indicator; Percutaneous coronary intervention; Quality indicator*

Indicateurs de qualité pour les interventions coronariennes percutanées au Canada

HISTORIQUE : En évaluant la conformité aux indicateurs de qualité, on obtient un paramètre de mesure directe de la qualité des soins à partir duquel celle-ci peut être améliorée. Toutefois, dans le cas des interventions coronariennes percutanées (ICP), on ne dispose pas encore de tels indicateurs de qualité au Canada.
OBJECTIF : Établir une série d'indicateurs de la qualité et des résultats de l'ICP qui pourraient être utilisés partout au Canada.
MÉTHODES : Un comité national d'experts composé de 12 membres a été formé pour représenter les pratiques dans différentes régions du Canada. Le comité a recensé les indicateurs potentiels de qualité en effectuant une recherche détaillée à partir des directives publiées, des rapports d'essais randomisés et des études sur les résultats de l'intervention. Une méthode de Delphes modifiée, en deux étapes, a été employée, avec une première sélection des indicateurs selon les cotes qui leur étaient attribuées, suivie d'une rencontre du comité national, puis de discussions en vue de l'atteinte de consensus.
RÉSULTATS : En tout, 26 indicateurs, dont six indicateurs structurels, neuf indicateurs liés au procédé et onze indicateurs relatifs aux résultats de l'intervention, ont été recensés par le comité national d'experts et jugés représentatifs d'une grande qualité des soins dans l'ICP. Les indicateurs pharmacologiques incluaient la prescription d'acide acétylsalicylique, de clopidogrel et de statine en traitement d'appoint à l'ICP. Les indicateurs non pharmacologiques incluaient des volumes minimes d'interventions, le délai entre l'arrivée et la pose du ballonnet dans l'ICP primaire, la prévention de la néphropathie induite par le produit de contraste et le choix des instructions et conseils au patient. Les indicateurs des résultats de l'intervention incluaient : mortalité, infarctus du myocarde, revascularisation du vaisseau cible et complications touchant l'accès vasculaire après l'ICP.
CONCLUSIONS : Une série d'indicateurs de qualité dans l'ICP devant être utilisée par le système de soins de santé canadien vient d'être mise au point. Pour la pratique clinique, l'adoption et l'application à grande échelle des indicateurs de qualité dans l'ICP faciliteront la reconnaissance des lacunes à combler et permettra d'améliorer la qualité et d'optimiser les résultats chez les patients qui subissent une ICP, partout au Canada.

Contemporary treatment of coronary artery disease frequently relies on invasive therapy with percutaneous coronary intervention (PCI) as an alternative to both medical therapy and coronary artery bypass grafting surgery (CABG) (1-3). In Canada and elsewhere, the number of PCI procedures has increased dramatically and PCI has become the most common means of coronary revascularization (4,5). The rapidly expanding volume of PCI procedures, however, has outpaced efforts to ensure that the procedures are being performed both effectively and efficiently. Indeed, recent studies have found substantial regional differences in post-PCI mortality across Canada, suggesting that there is an important opportunity to improve the quality of care and outcomes of PCI in all regions (6). Other data have also confirmed that substantial regional disparities exist in the utilization of cardiac invasive procedures (7-9).

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Received for publication April 20, 2008. Accepted August 17, 2008

TABLE 1
Structural indicators for percutaneous coronary intervention (PCI)

Structural indicator	Considerations
Minimum operator volume of at least 75 PCI procedures per year Minimum hospital volume of at least 400 PCI procedures per year	The minimum operator and hospital procedure volumes are determined by available data that showed consistent volume to outcome relationships. The panel is cognizant that some Canadian centres may not meet these targets due to unique situations. In these cases, the panel recommended an ongoing relationship between low-volume centres and high-volume centres
PCI centres performing primary PCI should track their door-to-balloon time and important time intervals for ongoing quality improvement feedback	Important components of the door-to-balloon time can include the door-to-electrocardiogram time, diagnosis-to-catheterization laboratory time and catheterization laboratory-to-balloon time. A hospital tracking system should be in place to record time intervals for continuous quality improvement in door-to-balloon time. A mechanism should be in place to report these times to hospital stakeholders within one week to ensure timely feedback and to identify areas for quality improvement
A standardized protocol should be in place to minimize contrast-induced nephropathy for PCI patients	Because no universally accepted prophylactic treatment against contrast-induced nephropathy is available, each hospital should have a standardized protocol to identify and initiate prophylaxis for patients at risk
A standardized protocol should be in place to ensure appropriate periprocedural antithrombin therapy during PCI	Many antithrombin therapies have been demonstrated to be effective as adjunctive therapy during PCI. However, it has also been shown that the use of these medications are prone to dosing error. Each hospital should have a standardized protocol to minimize the chance of medication errors
Standardized discharge plans should be established for PCI patients	Discharge planning should be comprehensive and include a discussion on the importance of compliance with dual antiplatelet therapy after stent placement, smoking cessation, diet modification and exercise to improve the overall outcome of PCI patients

Quality indicators or performance measures are defined as processes in which the evidence is so strong that failure to perform such actions reduces the likelihood of optimal patient outcomes (10). Quantifying adherence to quality indicators can therefore serve as a direct measure of the quality of care and provide a measurable target for quality improvement (10). Although efforts have been instituted to develop quality indicators for myocardial infarction, heart failure and CABG, there are currently no widely accepted standards on what constitutes high quality of care for PCI (11-13). Accordingly, the main objective of the present study was to develop a set of quality indicators for PCI that can be utilized across Canada.

METHODS

Modified Delphi panel process

A modified Delphi panel was used to develop quality indicators for PCI, in a similar process used to develop the Canadian myocardial infarction and heart failure quality indicators (11,12). The Delphi technique involves a survey process characterized by three features: anonymity, iterative and controlled feedback, and aggregation of responses. The intent was to minimize the impact of dominant panelists, limit irrelevant discussions and minimize group pressure to achieve a consensus (14,15).

Assembly of an expert panel

A 12-member panel was assembled to represent diversity in both medical expertise and geographic location. The panel members included two general cardiologists and eight interventional cardiologists from Alberta (MK), British Columbia (RC), Ontario (EC, SG, VD, KT), Quebec (SR), Nova Scotia (SF, ML) and the United States (BN). Discussions among the panel members were guided by two co-chairs with expertise in the Delphi panel process (DK, JT).

Literature review

The literature used to develop PCI quality indicators focused on practice guidelines from the American College of Cardiology and the American Heart Association on unstable angina and non-ST segment elevation myocardial infarction (non-STEMI) (2,16), STEMI (3,17) and PCI (1,18). In addition, extensive literature searches were performed to identify any existing PCI quality indicators, in addition to all relevant clinical trials and outcome studies relating to the process of care and outcomes of contemporary PCI practice.

Ratings

The panel members were asked to rate the PCI quality indicators on two separate occasions based on three major elements: interpretability, action-ability and feasibility. Before the first round of rating, each member was given a set of proposed indicators and related literature for review. All the potential structural and process indicators were rated using a scale from 1 to 5 using a standardized rating form, with a score of 5 indicating the highest rating. Outcomes indicators were rated as either 'yes' or 'no'. The prespecified criteria for inclusion of the potential indicators for the discussion at the national meeting was a mean overall rating greater than or equal to 3.5 for structural/process indicators and an agreement of at least one-half for outcome indicators. Indicators with lower overall scores were also considered if panelists believed that they warranted discussion.

After the initial rating, a face-to-face meeting was held on December 11, 2007 to allow the panel to discuss the potential merits and limitations of the retained indicators and to allow the opportunity to propose new indicators. A second rating was performed after the discussions. Measures that received a rating of 4 or above for structural and process indicators and an agreement of more than two-thirds for outcomes indicators for inclusion in the final set of indicators were included. The method of selecting performance measures in the present study was similar to the process supported by other professional societies (10,19). A follow-up conference call was held to refine the definitions of each quality indicator and to reconcile potential differences.

RESULTS

Selection of indicators

Of the 41 potential indicators, 26 received adequate scores and were discussed during the national panel meeting. At the meeting, nine new indicators were proposed by the panel members and were discussed in detail. All indicators underwent a second round of rating by the panel members. After further modification, 26 indicators including six structure indicators, nine process indicators and 11 outcomes indicators were selected by the national expert panel to be quality indicators for PCI (Tables 1 to 3).

TABLE 2
Process indicators for percutaneous coronary intervention (PCI)

Preprocedure processes	Numerator	Denominator	Method of reporting
Acetylsalicylic acid before PCI	All PCI patients who received acetylsalicylic acid within 24 h before procedure	Included: All PCI patients Excluded: Patients allergic to acetylsalicylic acid, documented reason for nonuse	Percentage of PCI patients who received acetylsalicylic acid before procedure
Renal function assessment before PCI	All PCI patients who have renal function assessment within one week before procedure	Included: All PCI patients Excluded: Emergent PCI (STEMI/rescue/cardiogenic shock) patients, documented reason for no renal function assessment	Percentage of PCI patients who have renal function assessed before procedure
Postprocedure process			
Cardiac biomarkers measurement after PCI	All PCI patients who have cardiac biomarkers (CK or CK-MB or troponin) measurement after procedure	Included: PCI patients and alive at hospital discharge Excluded: Documented reason for lack of postprocedural cardiac biomarker measurement	Percentage of PCI patients who have cardiac biomarkers measurement postprocedure
STEMI			
Door-to-balloon time in primary PCI	All patients who received primary PCI	Included: ST segment elevation or new left bundle branch block on ECG and PCI performed within 24 h after hospital arrival Excluded: Patients who received fibrinolytic therapy before PCI, documented reason for delay in primary PCI (eg, nonprimary PCI, late presentation, patient refusal)	Percentage of STEMI patients with door-to-balloon time of less than 90 min after hospital arrival* Median door-to-balloon time*
Processes at hospital discharge			
Acetylsalicylic acid at hospital discharge	All PCI patients who are prescribed acetylsalicylic acid at hospital discharge	Included: All PCI patients and are alive at discharge Excluded: Patients allergic to acetylsalicylic acid, documented reason for nonuse	Percentage of PCI patients who are prescribed acetylsalicylic acid at hospital discharge
Clopidogrel for bare metal stents (BMS)	All PCI patients who received BMS and who are prescribed clopidogrel for at least one month at hospital discharge	Included: All PCI patients who received a BMS and are alive at discharge Excluded: Patients allergic to clopidogrel, documented reason for nonuse	Percentage of PCI patients who are prescribed clopidogrel for at least one month at hospital discharge after BMS implantation
Clopidogrel for drug-eluting stents (DES)	All PCI patients who received a DES and who are prescribed clopidogrel for at least 12 months at hospital discharge	Included: All PCI patients who received a DES and are alive at discharge Excluded: Patients allergic to clopidogrel, documented reason for nonuse	Percentage of PCI patients who are prescribed clopidogrel for at least 12 months at hospital discharge after DES implantation
HMG-CoA reductase inhibitors (statins) at hospital discharge	All PCI patients who are prescribed a statin at hospital discharge	Included: All PCI patients and are alive at discharge Excluded: Documented reason for nonuse of statin (eg, rhabdomyolysis, liver disease or patient refusal)	Percentage of PCI patients who are prescribed statins at hospital discharge
Smoking cessation advice, counselling or therapy	All PCI patients with a smoking history who received smoking cessation advice, counselling or therapy during hospital stay	Included: All PCI patients and are alive at discharge Excluded: Documented reason for no smoking cessation advice or counselling (eg, patient refusal)	Percentage of PCI patients (smokers or recent history) who received smoking cessation advice, counselling or therapy during hospital stay

**Transferred patients to be reported separately. CK Creatine kinase; ECG Electrocardiogram; HMG-CoA 3-hydroxy-3-methyl-glutaryl-coenzymeA; STEMI ST segment elevation myocardial infarction*

TABLE 3
Outcome indicators for percutaneous coronary intervention

Outcomes
In-hospital mortality
30-day mortality
One-year mortality
Acute myocardial infarction readmission within one year
Emergency coronary artery bypass grafting surgery
Coronary artery bypass grafting surgery within one year
Target vessel revascularization within one year
Stent thrombosis
Renal failure requiring hemodialysis
Vascular repair (surgical and nonsurgical repair)
Blood transfusion (red blood cell)

Structural indicators for PCI

Operator volumes of 75 cases per year and hospital volumes of 400 cases per year were selected to represent minimum procedure volumes for safety and effectiveness of PCI procedures (Table 1). The panel recognized that these numbers were based on older studies performed in the United States and these procedure numbers were lower than the typical volumes of most Canadian PCI hospitals; however, these numbers were based on the best available evidence that showed a consistent volume to outcome relationship (1,20,21). Minimal volumes in primary PCI for the treatment of ST segment myocardial infarction were not selected as structural indicators because the majority of Canadian hospitals fulfilling minimal PCI procedure volumes likely also satisfy the minimal primary PCI volumes proposed in the United States (operator volume of 11 primary PCI, hospital volume of 36 primary PCI) (1). Given the geographical remoteness of some PCI programs, reflecting the distribution of the Canadian population, the panel recognized that it may be possible that some programs fall below these volume standards. The panel recommended that these low-volume hospitals should engage in a mentorship relationship with high-volume hospitals for potential guidance and quality assurance.

In hospitals that perform primary PCI for patients with STEMI, a hospital tracking system should be in place to record door-to-balloon time and other important time intervals for continuous quality improvement (Table 1). Reperfusion times should be reported back to hospital stakeholders within one week to identify areas for potential quality improvement.

Process indicators for PCI

The importance of adjunctive therapy for PCI was evident by the fact that the use of acetylsalicylic acid, clopidogrel and statin received almost unanimous support by the panel as quality indicators (Table 2). The panel also recognized the importance of preventing contrast-induced nephropathy and inappropriate dosing of antithrombotic therapy for PCI. However, the review of the literature did not support any specific therapy or combination; therefore, the panel recommended that a structured hospital-based approach with prespecified protocols should be in place (Table 1).

For patients with acute STEMI, a door-to-balloon time of less than 90 min was selected for a process indicator for primary PCI (Table 2). It is important to note that although door-to-balloon times are typically reported as a median value, the panel also recommended that the proportion of patients achieving a door-to-balloon time of less than 90 min be reported as a process indicator.

Outcomes indicators for PCI

Potential adverse outcomes of PCI such as death, myocardial infarction, target vessel revascularization and vascular complications were identified as outcomes indicators because of their clinical importance (Table 3). The panel recommended that unplanned CABG be distinguished from planned, staged CABG. For example, unplanned CABG is usually a reflection of complications arising from PCI and is often performed within 24 h of the index PCI. On the other hand, a planned, staged CABG may occur in a situation in which PCI was performed to provide initial stabilization (such as performing PCI in the infarct-related artery for patients with STEMI) in patients presenting with multivessel coronary disease.

DISCUSSION

The growing emphasis on accountability has increased the demands for understanding the performance of health care systems. Although PCI is the most common method of coronary revascularization in Canada and abroad, an operational definition for high quality of care from PCI procedures is not available. Accordingly, we engaged national experts to develop a set of quality indicators for utilization in the Canadian health care system. These PCI indicators were reviewed and formally endorsed by national organizations such as the Canadian Cardiovascular Outcome Research Team (CCORT), the Canadian Cardiovascular Society and the Canadian Association of Interventional Cardiology.

The development of PCI quality indicators represents a significant and necessary step in the promotion of quality of care. Our ultimate goal is to identify suboptimal practices, to reduce potential practice gaps and to improve procedural outcomes in Canada. Quality indicators differ from practice guideline recommendations. Guidelines are written to suggest diagnostic and/or therapeutic interventions but interpretation is required by the clinician to apply these recommendations for each patient (10). In contrast, quality indicators are those processes in which the evidence is so strong that failure to perform such actions reduces the likelihood of optimal patient outcomes (10). Quantifying adherence to quality indicators often serves as a foundation for quality improvement.

Our indicators include structural, process and outcome aspects to encompass the multidimensional construct of quality of care (22). The appropriate use of cardiac invasive procedures is an important aspect of quality of care. However, developing appropriateness criteria involves a different methodological approach by considering the risk-benefit tradeoff in a large number of clinical situations, which was beyond the scope of the present project. Furthermore, appropriateness guidelines for cardiac revascularization are being developed by other national societies such as the American College of Cardiology. Future efforts should perhaps focus on the adoption of appropriateness criteria in the Canadian context.

Some points raised by the panel members merit discussion. First, the panel voted in favour of target vessel revascularization and stent thrombosis as outcome indicators. However, these data elements are currently not routinely captured in the majority of Canadian jurisdictions. Nonetheless, the panel strongly believed that current limitations in obtaining key relevant data elements should not preclude the emphasis of their importance. Instead, the panel believed that its efforts should serve as stimulus for hospitals or regional systems to improve current data infrastructure to capture these important data elements. Second, because there is little information on the current adherence to these PCI quality indicators, our panel did not focus on establishing benchmark targets. Third, the panel recommended that more research be done specifically in the Canadian setting to better determine what the minimum annual operator and hospital PCI volumes should be to ensure optimal patient outcomes.

Finally, while other countries such as the United States and the United Kingdom have made quality improvement a strong priority, and allocated resources and implemented mandatory reporting of PCI processes and outcomes, the Canadian health care system has devoted relatively limited resources to date for such initiatives. The panel discussed the importance of capturing good quality data in a comprehensive and continuous manner because they are the foundation of quality improvement. Obtaining quality data will not be possible without the support of patients and practising physicians, and the availability of adequate funding from sources such as provincial Ministries of Health from across Canada.

SUMMARY

For the first time in Canada, we have developed a set of PCI quality indicators by using a modified Delphi panel method. The quantification of practice gaps through adoption of these PCI quality indicators will provide opportunities to improve the treatment and outcomes of patients undergoing PCI throughout Canada.

ENDORSEMENTS: Endorsed by the Canadian Cardiovascular Outcomes Research Team (CCORT), the Canadian Cardiovascular Society and the Canadian Association of Interventional Cardiology.

ACKNOWLEDGEMENTS: This work was supported by a Canadian Institutes of Health Research Team Grant in Cardiovascular Outcomes Research to the CCORT and a Canadian Institutes of Health Research operating grant. Dr Ko is supported by a Clinician-Scientist award from the Heart and Stroke Foundation of Ontario. Dr Tu is supported by a Canada Research Chair in Health Services Research and a Career Investigator Award from the Heart and Stroke Foundation of Ontario. Dr Wijeysundera is supported by the University of Toronto's (Ontario) Department of Medicine Clinician-Scientist Training Program and a research fellowship from the Canadian Institutes of Health Research.

ROLE OF THE SPONSORS: The results and conclusions are those of the authors and should not be attributed to any funding or sponsoring agencies. All decisions regarding study design, publication and data analysis were made independent of the funding agencies.

DISCLOSURES: Dr Džavík received research grant support and/or speaking/consulting honoraria from Abbott Vascular, Abiomed, Cordis Corporation, Johnson & Johnson and Datascope Corp. Dr Goodman received research grant support and speaking/consulting honoraria from Abbott Canada, AstraZeneca Canada Inc, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline Inc, Hoffmann-La Roche Ltd, Johnson & Johnson, Key Schering/Schering Plough, Merck Frosst, Pfizer, sanofi aventis and The Medicines Company. Dr Rinfret received honorarium for lectures and advisory board from Abbott Vascular and Cordis Canada, and received a research grant from Cordis Canada. Other authors have no relationships to disclose.

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