CHANGES IN REFERRAL PATTERNS FOR CORONARY REVASCULARIZATION: THE IMPACT ON CORONARY ARTERY BYPASS GRAFTING SURGERY









## Title Page

# CHANGES IN REFERRAL PATTERNS FOR CORONARY REVASCULARIZATION: THE IMPACT ON CORONARY ARTERY BYPASS GRAFTING SURGERY

by

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#### Abstract

#### Background:

Across Canada, waiting times for cardiac procedures, such as coronary artery bypass grafting (CABG), are higher than the ideal waiting time. From 1994 to 2002, there was a rapid increase in the number of patients receiving cardiac catheterizations and CABGs across Canada. The rates in Newfoundland and Labrador (NL) were higher than the Canadian average. This resulted in an extremely long waitlist with patients waiting longer than the acceptable benchmark time to have their surgery. In 2004, the number of people in Canada on cardiac surgery waitlists decreased significantly more than would be expected from simple waitlist management. The main reason is that the number of referral rates for CABG dropped dramatically. One major reason for this drop in referral rates may have been due to the introduction of drue-cluting stents in Canada in 2003.

#### Objectives:

The objective of this study is to identify changes in referral patterns for coronary revascularization and assess the impact on CABG waiting times in NL. This retrospective study will identify the changes that occurred during this time period and determine the reason(s) for these changes.

## Method:

All 1341 patients who underwent a diagnostic cardiac catheterization in NL from April 1, 2005 to September 30, 2005 were included in this study. Records from the Cardiac Program of Eastern Health were reviewed to determine referral rates, utilization rates, and wait times for percutaneous coronary intervention (PCI) and CABG procedures from 1998/1999 to 2007. The data obtained was compared to data from 1998/1999.

#### Results:

From 1998/1999 to 2005/2006 the number of coronary eatheterizations increased by 21.6%. This was attributable to increased numbers of patients with stable angina, myocardial infarction or chest pain of uncertain etiology, treated not by revascularization procedures but by medical management. The proportion of patients diagnosed with critical coronary artery disease (CAD) decreased by 5%. Patients with critical CAD were referred for medical management, PCI, CABG or other. Referral rates increased 8.3% for medical management, decreased 4.8% for PCI, decreased 5.1% for CABG and increased 1.6% for other.

Between 2003 and 2007 the number of CABGs decreased by 12.7% and angioplasty increased by 8%. In 2002, the year prior to introduction of drug-eluting stents (DES), 50% of those referred for revascularization were treated with PCI compared to 59% in 2007. Within one year of the introduction half of all stents comprised DES. Total stent use has increased with an increase in DES and a decrease in bare metal stents (BMS). In 2005, 63% of stent cases received DES compared to 13.3% in 2003. Increased use of PCI for unstable angina was observed in 2005 compared to 1998/1999 (73% v 61%), but its use in those with multi-vessel disease was similar in both years.

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From 2002 to 2007, the number of CABGs performed had an overall decrease from 568 to 492, and the waiting list went from 222 to 78. The recommended maximum waiting time (RMWT) for CABGs are being reached for most patients in the semi-urgent (<2 weeks), short wait (<6 weeks), delayed wait (<6 weeks) and marked delay (<6 months) priority groups. More than 80% of the patients in these groups are getting CABGs on time. For very urgent (<24 hours) and urgent (<72 hours) patients, the percent reaching the target for the RMWT is less than 50% but has increased since 1998/1999.

#### Conclusion:

The number of coronary catheterizations performed each year continues to grow, however, the proportion diagnosed with critical CAD (69%) has decreased. CABG numbers decreased at the time when DES utilization increased. Management of CAD in the twenty-first century has changed rapidly. The rapid incorporation of DES in practice has helped alleviate the problem of large CABG waitlists.

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## Chapter 1 Introduction

## 1.1 Background

Management of coronary artery disease (CAD) has changed rapidly in the twenty-first century. There has been a move away from coronary artery bypass graft (CABG) surgery to less invasive procedures such as percutaneous coronary intervention (PCI) and coronary artery stenting. Drug-eluting stents (DES) were introduced first in Europe in 2001, then in both Canada and the US in 2003 (1, 2, 3). DES have lower restenosis rates than BMS (5% vs 12-20%, respectively) by incorporating a drug such as paclitaxel, sirolimus, or everolimus that inhibit smooth muscle proliferation and prevent reocclusion of the vessel (4, 5). When compared to CABG surgery, DES allow avoidance of general anaesthesia, sternotomy and cardiopulmonary bypass. DES and CABG have similar one year mortality rates, but BMS require more frequent revascularizations (6). The introduction of DES has been associated with decreased use of CABG (7, 8, 9, 10).

In Europe, between 1994 and 2002, coronary catheterizations increased 3.2-fold, and PCI increased six-fold with 85% of those patients receiving stents (1). Since 2001, 26% of patients who received stents had DES while the rest had bare-metal stents (BMS). In Europe and the United States, the indication for PCI has shifted toward acute coronary syndromes with increasing rates of interventions for acute MI and multivessel disease (1, 11). In the US, there has also been a rise in DES use and a decrease in CABG for unprotected left main stenosis (12).

Utilization of CABG surgery and PCI with bare metal stent (BMS) insertion rose dramatically across Canada from 1988 to 2002, including in Newfoundland and Labrador (NL) (13, 14, 15). This led to increasing wait times for CABG and PCI both in Canada and NL.

The increasing utilization of coronary catheterization, along with the increasing number of people diagnosed with critical CAD, has exacerbated the problem of long waiting times for cardiovascular services in Canada. In NL, several studies have confirmed the need to increase funding for cardiovascular services. Prior to the introduction of DES in 2003, the number of CABG surgeries performed had an overall increase from 437 in 1998/1999 to 626 in 2001/2002. In 1998/1999, however, the proportion of patients who had CABG within the recommended maximum wait time was not optimal (14, 16). Optimal wait time was determined by a priority ranking that was calculated using the pattern or severity of angina symptoms, the coronary artery anatomy and the results of noninvasive tests of ischemic risk (17,18). The cases were categorized as follows: very urgent (should undergo surgery within 24 hours), urgent (should undergo surgery within 72 hours), semi-urgent (should undergo surgery within 14 days during the same hospital stay), short elective list (should undergo surgery within 6 months).

In 2004, the first Ministers increased funding for cardiovascular services in Canada (19, 20). This was a ten year plan created to strengthen health care delivery. One of the main objectives was to provide better management of wait times and reduce wait times where

they were longer than medically acceptable. Five priority areas were identified including cardiac care. A Wait Time Reduction Fund was established for \$5.5-billion to augment existing provincial and territorial investments and to assist jurisdictions in their own particular initiatives to reduce wait times. The terms of this agreement were:

- Each jurisdiction agreed to establish comparable indicators of access to health care professionals, diagnostic and treatment procedures with a report to their citizens to be developed by all jurisdictions by December 31, 2005.
- Evidence-based benchmarks for medically acceptable wait times were to be established by December 31, 2005.
- Multi-year targets to achieve priority benchmarks were to be established by each jurisdiction by December 31, 2007.
- Provinces and territories were required to report annually to their citizens on their progress in meeting their multi-year wait time targets.

The Wait Time alliance was formed in 2004 to develop acceptable benchmarks and makes several recommendations on ways to realize wait-time benchmarks and improve patients' access to care. The NL benchmarks for CABG surgery were set at 2 weeks for semi-urgent, 6 weeks for short wait and, 26 weeks for delayed wait patients (21). Timeline:

1988-2002:	CABG and PCI wait times increase
2001:	DES introduced in Europe
2003:	DES introduced in Canada and US
2004:	First Minister's meeting to develop 10 year plan to reduce wait times
2005:	NL benchmark set for CABG set according to the Wait Time Alliance
2005:	Cohort of patients undergoing cardiac catheterization included in study

The current study was undertaken (a) to examine the utilization of cardiovascular services for CAD following the introduction of DES in 2003, (b) to compare the clinical characteristics of those who had coronary catheterization and critical CAD diagnosed in 2005 and 1998/1999, (c) to determine the clinical factors which influenced the management strategy of critical CAD in 2005, (d) to compare the clinical characteristics and wait times of those referred for CABG in 2005 to those in 1998/1999, and (c) to assess the clinical characteristics of those who were treated with DES to those who received bare metal stents in 2005.

We hypothesized that following the introduction of DES in NL in 2003 there would be increased utilization of PCI that would be associated with decreased utilization of CABG, especially in those presenting with unstable angina and in those with multivessel disease. We also hypothesized that CABG wait times would improve as a result.

## 1.2 Purpose

- To identify all patients who underwent a diagnostic cardiac catheterization from April 1, 2005 to September 30, 2005.
- To determine the proportion of patients who underwent cardiac catheterization and were diagnosed with critical CAD.
- To determine if the proportion of those patients diagnosed with critical CAD by cardiac catheterization has changed since 1998/99.
- 4. To identify treatment recommendations for patients with critical CAD.
- To determine if treatment recommendations for patients with critical CAD have changed since 1998/99.
- To determine the clinical factors that influenced the management strategy of critical CAD.
- To determine if the introduction of DES has impacted referral practices for coronary revascularization.
- 8. To determine urgency rating scores for patients referred for CABG.

9. To determine recommended and actual wait times for CABG.

## 1.3 Significance

This research will identify the changes that occurred during the time period from 1998/1999 to 2005 and determine the reason(s) for these changes, and whether the use of DES was consistent with indications. The contributions it could make include future planning of wait list management systems and allocation of resources.

## Chapter 2 Review of Literature

#### 2.1 Summary

A literature review was carried out using PubMed as the primary resource. MeSH Database searches were used to find keywords. Articles were limited to English language, human subjects and all adult categories. Section one of the literature review will focus on the indications for each of the revascularization methods including CABG and PCI as well as indications for medical management of critical CAD and whether one method is preferred over another. In sections two and three, respectively, changes in referral patterns for these treatments will be reviewed as well as the utilization of cardiac services in NL and Canada. The focus of section four will be waiting times for PCI and CABG both in NL and Canada. Finally, section five will examine how medical therapies and drug-eluting stents have changed referral patterns for CABG.

## 2.2 Revascularization versus medical therapy for treatment of critical coronary artery disease

Critical CAD is defined as a reduction of 70% or greater in the luminal diameter of the right coronary artery (RCA), the left anterior descending artery (LAD), the circumflex artery and/or their major branches (17, 18). The definition also includes a reduction of 50% or greater in the luminal diameter of the left main coronary artery (LMCA). There are three treatment options for patients who are diagnosed with critical coronary artery disease (CAD) via cardiac catheterization. They are percutaneous coronary intervention (PCI) with the use of a balloon or stent, coronary artery bypass grafting (CABG) surgery

and medical management. There are no clear indications for the use of any one method, as the best option for each individual patient is different. Clinical circumstances, available revascularization options, and patient preferences need to be taken into consideration. As technologies change, referral patterns for different treatment options may change.

Revascularization procedures include CABG which is the most invasive method and percutaneous coronary intervention (PCI) using a balloon or stents. CABG was preferred over PCI in multivessel and LMCA disease as well as in those with comorbid valvular heart disease. CABG is normally the standard of care in patients with triple vessel or LMCA disease, however, mortality rates and adverse outcomes such as death, myocardial infarction or stroke are not different in the two groups (22, 23). PCI and CABG have similar mortality rates but PCI has a higher restenosis rate requiring revascularization with either repeat PCI or CABG (24). Elderly patients have more deaths in the first 6 months with CABG, as compared to PCI, but have better long-term survival (25). In patients with previous CABG surgery, PCI is the preferred method of revascularization (26).

Stenting can be done using either bare metal stents (BMS) or drug-eluting stents (DES). Drug-eluting stents were introduced to try and relieve the problem of restenosis in patients receiving stents. Sirolimus and paclitaxel are the two main drugs that coat the DES to decrease restenosis. There was improvement in restenosis rates compared to

BMS but the rates are still higher in DES when compared to CABG. Studies comparing DES to CABG have shown that mortality rates are the same but restenosis rates are higher in the DES groups (27). Early studies of CABG versus DES showed that in the short term (30 days), mortality was the same in both groups but the DES group had a higher restenosis rate requiring repeat revascularization procedures (28). These results have been reproduced for longer term studies (1-5 years) as well (29, 30, 31, 32, 33). Results of studies comparing BMS to CABG show similar results (34). DESs are associated with a greater number of stents placed, more areas stented and more bifurcation stenting compared to BMS. Patients with high-risk unstable angina whose age was greater than 70 years and had medically refractory ischemia, those with LV dysfunction, and those with cardiogenic shock had no mortality difference when given either CABG or PCI (35, 36, 37). For patients with unprotected LMCA disease treated with either DES or CABG, no differences in cardiac or cerebrovascular events were found (38). LMCA patients who received DES had lower rates of MI and fewer repeat revascularizations compared to those with BMS (39, 40, 41).

Studies have shown that DES have lower restenosis rates in the first year than BMS but mortality was the same (42, 43, 44). After a three year follow up period, it has been shown that the restenosis rates were no different in the DES and BMS groups (41). Other studies have shown that patients treated with DES had lower rates of acute MI and death (45, 46). In patients who have had ST elevation MI (STEMI) there were no differences in mortality or recurrent MI when comparing DES to BMS (47). Some early small studies

found that there was an increased risk of stent thrombosis with DES, however, in larger randomized trials this was not shown to be a complication of DES compared with BMS (48). In diabetic patients receiving PCI, significantly less in stent restenosis and fewer major cardiac adverse events, including death, MI and stroke, were observed (49). In patients with severe renal insufficiency (creatinine clearance <40 ml/min) target lesion revascularization was similar for DES and BMS (50).

Medical management of patients with CAD includes four standard medication classes: antiplatelet agents (aspirin, adenosine diphosphate receptor antagonists, or dipyridamole.), beta-blockers, inhibitors of the renin-angiotensin system (angiotensinconverting enzyme inhibitor or angiotensin receptor blocker), and statins or other lipidlowering agents (51, 52). One large scale study revealed that having previous revascularization procedures was associated with better use of these four guidelinerecommended medical treatments (53). A study comparing medical management with PCI reported that in patients with chronic stable CAD, no significant differences between the two treatment strategies were observed with regard to mortality, MI, or CABG or PCI during follow-up (54). In patients with STEMI, the rates of repeat MI are higher with medical management than with revascularization (55). Patients have better outcomes with revascularization over medical management if they are male, non-smokers, and have two or more risk factors (55). One study showed that optimal medical therapy significantly reduces myocardial ischemia; however, PCI combined with medical therapy produces an even greater reduction in ischemia (56).

The three treatment modalities can be used interchangeably and the method used depends on multiple factors including the clinical situation, patient preference and availability of the treatments. There are no clear guidelines as to which method should be used and research in this area is ongoing.

#### 2.3 Changing referral patterns in NL and Canada

There have been numerous changes in the wait lists across Canada for many years. Multiple factors have influenced the number of people on the wait lists including changes in wait list management, actual waiting times for cardiac procedures and new technologies developed for cardiac patients. CABG rates in Ontario increased by greater than 30% between 1979 and 1983 and then remained stable through to 1988 (57). Reasons cited for the large increase in CABG rates include an increasing elderly population, increased use of diagnostic testing which would pick up critical CAD, and increased use of facilities as elderly patients have longer stays in Intensive Care Units (57, 58). With increased funding providing more efficient service and increased patient capacity and the introduction of percutaneous transluminal coronary angioplasty (PTCA), the wait list in Ontario decreased (57). Between 1988 and 1991, cardiac catheterizations increased across the country by 8.5% but the wait time for this procedure did not change (13). During that same time period, the rate of PTCA increased by 38.5% and the rate of CABGs increased by 20.6% (13).

In 1991 a panel of cardiologists and cardiac surgeons in Canada derived principles for ranking patients with critical CAD who require CABG (18). In Ontario, from 1991 to 1993, patients rarely suffered critical events such as death or MI while waiting for CABG and did not have extreme delays in recieving CABG surgery (59). From 1994 to 2002, there was a rapid increase in the volume of patients receiving cardiac catheterizations and CABGs across Canada (14). Cardiac catheterizations increased 85% during that time period and CABG increased approximately 20% (61). Rates of CABG in Newfoundland were consistently higher than the Canadian average. From 1997 to 2002, the age standardized rate of CABG in Canada ranged from 94.3 to 95.8 while NL ranged from 117.1 to 142.2 (62). This meant that the waitlist became extremely long and patients had to wait longer than the acceptable benchmark time to have their surgery (14). Many patients were sent to the United States to have the procedure done within an acceptable time period (63). Many reasons have been proposed for the long waiting times for CABG in Canada including lack of human resources, lack of infrastructure such as limited equipment and limited operating time, poor system management, poor coordination of services, and increased demand (19).

In 2004, the number of people in Canada on cardiac surgery waitlists decreased significantly more than would be expected from simple waitlist management. This was also observed in NL (64). There are a number of hypothesized explanations for this trend including the introduction and increased use of DES, changing population demographics, better medical therapies and a trend toward positive lifestyle changes. According to

Sobolev et al, as waiting lists decrease, the waiting time should also decrease (65). However, compared to 1993, the waiting time in 2004 was 92% longer (64).

#### 2.4 Utilization of Cardiac Services in NL and Canada

In NL between April 1, 1994 and March 31, 1995, 1604 patients had a coronary catheterization done and of those, 1082 had critical CAD (16). Twenty-five percent of those patients were referred for PCI, 36% were referred for CABG, and 33% were treated with medical management. CABG was performed on 338 patients that year. Of these, 98.8% were considered appropriate and 93.8% were considered necessary. The numbers of patients who underwent CABG in the recommended time were 24% of the urgent patients, 64% of the semi-urgent patients, 50% of the short wait patients, and 75% of the delayed wait patients. Most of the patients receiving CABG presented with late-stage angina symptoms and advanced CAD. Based on these results, the government of NL increased funding to decrease wait times and the wait list size. However, the health care delivery system was slow to provide the capacity to meet the demand.

Between 1994/1995 and 1998/1999 the number of coronary eatheterizations increased by 37% and the number diagnosed with critical CAD increased from 64% to 74% (14). The proportion of patients referred for PCI increased to 39%, medical management decreased to 24% and CABG referrals stayed the same at 36%. More patients referred for CABG were less acutely ill while PCI was used to treat the more acutely ill. CABG was deemed necessary in 95% of patients. In 1994/1995, 47% of patients received their CABG within

the recommended wait time while this decreased to 39% in 1998/1999, with the delayed wait patients having the largest decrease in the proportion of patients who received surgery within the recommended wait time.

The number of revascularization procedures has not changed significantly from 2004 to 2007 in NL (60). In 2002/2003 the rate of CABG was 42 per 100 000 adults (62). In 2007/2008 the rate of CABG was 105 per 100 000 adults. In NL in 2007/2008, 58% of coronary revascularization was done using PCL

In Canada, the overall cardiac revascularization rate increased by 39% per 100 000 population from 1998/1999 to 2005/2006 (62). The rate went from 187 to 259 per 100 000 population. Since 2005/2006 the rate has started to decrease. Rates of CABG went down by 2.8% and PCI increased by 66% from 1998/1999 to 2002/2003 (15). PCI went from 96 per 100 000 in 1998/1999 to 177 per 100 000 in 2005/2006. The rate of CABG decreased by 18% from 1998/1999 to 2007/2008 from 91 to 75 per 100 000. Across Canada in 2002 and 2003 the rate of CABG was 71 per 100 000 adult population and the rate of PCI was 143 per 100 000 adult population (19).

#### 2.5 Wait time Benchmarks for CABG in NL and Canada

In September 2004, the First Ministers developed an agreement to increase funding across Canada and to achieve acceptable wait times for cardiac procedures. Benchmarks for CABG have been developed by the Wait Time Alliance and are presented in Table 1 (19).

## Table 1: Wait time benchmarks for CABG<sup>1</sup>

Urgency category	Target	Benchmark
Emergency (unrelenting cardiac compromise unresponsive to all therapy except surgery)	< 90 minutes	< 4 hours
In house urgent (unable to be discharged due to need for intravenous nitroglycerine, heparin, or intra-aortic balloon pump (IABP))	1 day	7 days
Urgent outpatient	7 days	14 days
Non-urgent outpatient	6 weeks	6 weeks

<sup>1</sup>Wait Time Alliance for Timely Access to Health Care. (2005). It's about time! Achieving benchmarks and best practices in wait time management. Ottawa, ON: Canadian Medical Association.

These benchmarks are guidelines only and do not take into account any constraints on the capacity to meet these benchmarks. More realistic pan-Canadian benchmarks were set by provincial and territorial governments. The NL government decided to set the benchmark for CABG surgery at 26 weeks for delayed wait, 6 weeks for short wait and 2 weeks for semi-urgent patients. In Newfoundland, between July 1 and September 30 of 2006, 97.8% of CABG cases were completed in 182 days (26 weeks) (66). Information regarding other priority groups was not available.

Studies have shown the outcomes of being on a waiting list for CABG negatively impact patients including reduced employment and income, physical stress, lack of social support, frustration, and decreased quality of life (67, 68, 69, 70, 71, 72, 73). When patients' surgeries are postponed they are more likely to feel anger and disappointment, have additional tests conducted, procedures performed and medications prescribed, which may lead to extended hospital stays and increased costs (74). Therefore it is not only important for patients to have their procedures done within the benchmark for their health and safety but also to minimize hospital and other healthcare costs. Risk factors that have been shown to contribute to death while waiting for CABG are impaired left ventricular function, advanced age, male sex and waiting longer than the recommended maximum wait time (RMWT) (75).

#### 2.6 Effect of drugs on referral patterns

There are three options for patients who are diagnosed with critical CAD: medical therapy, which includes drug therapy and lifestyle modifications, percutaneous coronary

intervention (PCI) and CABG. CABG is the most invasive therapy and there is a long waiting list for the procedure. It may be possible that with the introduction of newer drugs and more effective PCI, less CABGs need to be performed in order to achieve the same effectiveness. Drug therapy should be given to all CAD patients and is generally the primary option for patients with stable, low-risk CAD (76). The major classes of drugs for patients with stable angina are nitrates, beta-blocker, and calcium channel blockers while those with unstable angina also include intravenous heparin and intravenous nitroglycerin (77). A study examining the impact of new cardiac interventions, including drugs, PCI and CABG, over the past 30 years found that they all decreased cardiovascular mortality (78). However, CABG led to a 44% reduction in total mortality. STEMI, or refractory angina requiring revascularization in patients with stable multivessel CAD (79). While medical therapy can decrease mortality, CABG is clearly better in stable patients. However, one European study reported that patients with stable coronary artery disease who underwent revascularization procedures (CABG or PCI), had more severe angina and an increased area of myocardium at risk (26).

Data on seniors who are on public drug programs in five provinces showed an increase in the age and sex standardized rate of cholesterol lowering drugs by 79% between 2001/2002 and 2007/2008 (80). Statins have been shown to improve vein graft patency, minimize recurrent ischemic events, and decrease the need for repeat revascularization procedures in patients who have undergone CABG (81, 82). This could potentially decrease the need for CABG procedures and therefore decrease the waiting list size and waiting time.

#### 2.7 Effects of drug-eluting stents on referral patterns

Drug-eluting stents are one of the treatments for critical CAD. They are placed in the diseased artery and release a drug, either sirolimus or paclitaxel, which reduce the incidence of restenosis of the artery. The use of drug-eluting stents allows avoidance of general anesthesia, sternotomy, and cardiopulmonary bypass (83). They were first used in NL in 2003. In-stent restenosis occurs in 12-20% of patients receiving bare-metal stents (BMS) while it only occurs in approximately 5% of patients with DES (4). Patients with multiple vessel disease treated with CABG and those receiving DES showed no differences in mortality at one year, however, patients treated with CABG required fewer revascularizations (6). Since it is a relatively new procedure, long-term outcomes are still unknown. Because this procedure is less invasive and takes less time to perform, it is predicted that physicians will refer more patients for DES than CABG. This would decrease the amount of CABG surgeries performed. One study showed that the introduction of DES decreased cardiac surgery volume by 21% (7). The most common predictors of a referral change from CABG to PCI with DES were diffuse coronary narrowing, restenotic lesions, and small coronary arteries (7). Other studies have shown modest decreases for CABG referrals after the introduction of DES (8, 9, 10). Long-term outcomes of DES are required to determine whether long-term changes in referral patterns for CABG will occur and whether patient outcomes are better with DES or CABG

## Chapter 3 Research Design

This is a retrospective study to determine whether physician referral patterns for coronary revascularization have changed from 1998/1999 to 2005, and if they have, what was the effect on number of CABG surgeries performed. The study protocol was approved by the Human Investigation Committee at Memorial University of Newfoundland, St. John's and by the Research Proposal Approval Committee, a sub-committee of the Medical Advisory Committee, Eastern Health, St. John's.

#### 3.1 Utilization

All patients who underwent a diagnostic cardiac catheterization from April 1, 2005 to September 30, 2005 were included in this study. This data was obtained from the manager of the cardiac catheterization laboratory at the Health Sciences Centre, St. John's, NL. 1341 patients were identified as having had a cardiac catheterization during this period. The records on cardiac catheterization, PCI, and CABG at the Cardiac Program of Eastern Health were reviewed to determine the referral rates, utilization rates, and wait list times for these procedures from 1998 to 2005. This program is the sole provider of these services in NL, which had a population of 424,155 aged 15 years and older in the 2001 census (84).

## 3.2 Data Collection

From April 1 to September 30, 2005, an incident cohort of all patients having diagnostic cardiac catheterization during that period was identified. Demographic, clinical and diagnostic test data were collected as were records of the decisions made at the weekly cardiovascular conference by cardiologists and cardiac surgeons regarding the type of intervention to be applied to patients with critical CAD. Data was obtained from notes from the cardiac catheterization procedure, the cardiovascular surgery conference and the surgery itself, discharge summaries and letters of consultation, as well as results of investigations such as stress tests and echocardiography. Data collected from patients who had a cardiac catheterization included age, gender, indication for heart catheterization, and whether the patient had critical CAD. Data from 1998/1999 was obtained from previously published data (14).

## 3.3 Definitions

The definitions for unstable angina, angina class, asymptomatic CAD, significant CAD, maximum medical therapy, results of noninvasive tests, coronary artery anatomy and indications for cardiac catheterization or CABG were those approved by the RAND Corporation Ratings of appropriateness and necessity by a Canadian panel (17, 18, 77, 85), and used in the previous studies (14, 16) in 1998/1999 and 1994/1995.

Possible indications for heart catheterization were stable or unstable angina, MI, chest pain of unknown origin, coronary heart failure (CHF), and other. For patients who had non-critical CAD, no more data collection was required.

For patients who had critical CAD, data that was collected included coronary anatomy, Left ventricular (LV) angiogram, ejection fraction (EF), comorbid diabetes mellitus types I and II, Canadian Cardiovascular Society (CCS) angina class, very positive stress test, maximal medical therapy, and recommendations for treatment. This data was obtained using the computer-based Meditech system.

Coronary anatomy is based on the number of coronary arteries affected and their location. Single vessel disease is critical CAD in at least one of the LAD, RCA, or circumflex arteries. Double vessel disease is critical CAD in two of the LAD, RCA, or circumflex arteries. PLAD involvement means there is critical CAD proximal to the first septal perforator. Triple vessel disease is critical CAD in all three of the LAD, RCA, and circumflex arteries. Protected left main disease is critical left main CAD in the presence of a patent bypass graft to the LAD or circumflex arteries, or by collateral flow to these arteries from a patent RCA. Unprotected left main disease is critical left main CAD in the absence of any patent grafts to the LAD or circumflex, or collateral flows to these arteries from the RCA. Choices for coronary anatomy for data abstraction purposes were:

1. Single vessel disease, no proximal LAD (PLAD) involvement:

2. Single vessel disease with PLAD involvement

3. Double vessel disease, no PLAD involvement

- 4. Double vessel disease with PLAD involvement
- 5. Triple vessel disease
- 6. Unprotected left main disease
- 7. Protected left main disease

A left ventricular angiogram measures the left ventricular ejection fraction (EF), which is the fraction of blood pumped out of the ventricles with each heartbeat. It has been shown that patients with a low EF (<40%) have an increased mortality rate post CABG (86). Ejection fraction data was used to determine the grade of the ventricle.

1. Grade 1 ventricle - EF of greater than or equal to 50%.

2. Grade 2 ventricle - EF greater than or equal to 35% but less than 50%.

3. Grade 3 ventricle - EF of greater than or equal to 20% but less than 35%.

4. Grade 4 ventricle - EF of less than 20%.

CCS angina class has been in existence since 1976 and is used to determine the severity of angina associated with activity. Table 2 lists the criteria for each angina class. Grade IV angina is considered unstable.

# Table 2: Canadian Cardiovascular Society Angina Grading Scale (87)

Grade	Description
Grade I	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation.
Grade II	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one light of ordinary stairs at a normal pace and in normal conditions.
Grade III	Marked limitation of ordinary physical activity. Walking one or two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace.
Grade IV	Inability to carry on any physical activity without discomfort, anginal syndrome may be present at rest.
Stress testing is a non-invasive measure for diagnosis and risk stratification of myocardial ischemia. It has a sensitivity of 68% and specificity of 77% (88). A very positive stress test has a positive predictive value of approximately 50% for left main or triple vessel disease. A very positive stress test is defined as having one or more of the following criteria (18):

- 2.5 mm ST depression
- ST elevation >1 mm in leads without q waves
- low workloads (heart rate <120)</li>
- early onset ST segments in 1<sup>st</sup> stage (3 min)
- · ST segment depression lasting longer than 8 minutes into recovery stage
- maximum heart rate >120 on cardio-inhibitory medication
- SBP lowered at least by 10 mmHg
- ≥ 3 beats of ventricular tachycardia
- · new resting changes and/or reversible changes with pain
- high thallium: Suggest either anterior wall or multiple areas of myocardia to be in ischemic ieonardy
- high halter monitor: For ambulatory ECG monitoring, shows prolonged and unequivocal ischemia.

Maximal medical therapy for stable angina includes patients who have received drugs from at least two classes including beta-blockers, nitrates, and calcium channel blockers or the patient is only on one of these drugs and is unable to tolerate the others (18).

Maximal medical therapy for unstable angina is defined as meeting one of the following criteria (18):

 The patient must have received drugs from at least two classes including betablockers, nitrates, calcium channel blockers, and intravenous (IV) heparin, or,
 The patient must be receiving IV nitroglycerin, or
 The patient must be receiving one class of drugs in (1) above and is unable to tolerate

the others.

Recommendations for treatment of critical CAD included medical management, PCI, CABG, or other. For patients whose recommended treatment was either medical management or other, no further data collection was required. For patients whose recommended treatment was PCI, it was determined whether the patients had a coronary stent inserted. If there was a stent insertion, then it was determined whether the stent inserted was a BMS or a DES. For patients recommended for CABG, a more extensive data collection was required. Clinical characteristics of patients diagnosed by cardiac catheterization with critical CAD in 1998/1999 and clinical characteristics of patients referred for CABG in 1998/1999 were compared to data from 2005.

#### 3.4 Priority scoring

Using a priority score developed by consensus, patients referred for CABG were ranked according to need (14). The pattern or severity of angina symptoms, the coronary artery anatomy and the results of noninvasive tests of ischemic risk determined the priority ranking. Priority for CABG was calculated and waiting times for CABG were recorded. Data from April 1, 1998 to March, 1999 (12 months) were compared with those collected in 2005 (6 months). The data from 1998/1999 came from a previous prospective study with data collection occurring at the time of catheterization (14). This approach was not feasible for this study due to limited resources.

The date accepted for CABG and the date of the CABG were used to calculate the number of days awaiting CABG. An Urgency Rating Score (URS) was then calculated for these patients. This was calculated using the Cardiac Care Network of Ontario URS Calculator (89). This calculator includes data such as CCS angina class, vessel disease, LV function, ischemic risk, co-morbidity, recent MI within 30 days of acceptance to surgery, and previous CABG surgery.

From the URS, a RMWT was calculated. Patients were then categorized into priority scales with RMWT as follows: Very urgent (patient should undergo surgery within 24 hours), urgent (should undergo surgery within 72 hours), semi-urgent (should undergo surgery within 14 days during the same hospital stay), short wait (should undergo surgery within 6 weeks), delayed wait (should undergo surgery within 3 months) and marked delay (should undergo surgery within 6 months). By comparing this categorization with the length of time the patients actually waited for CABG, it was possible to make an indirect assessment of the efficiency with which the cardiac surgery program delivers CABG in NL. This data was compared to data from 1998/1999.

Coronary revascularization utilization data from 1998/1999 were compared to the data from 2005. The number of cardiac catheterizations was obtained and the percentages of those who were referred for CABG and PCI were calculated. The amount of CABGs done and the number of people on the wait list was also obtained. The annual growth or decrease in cardiac catheterizations, CABG surgeries and PCIs was calculated and compared from 2005 to 1998/1999.

All statistical analyses were carried out using Statistical Package for Social Sciences (SPSS) version(s) 12.0 and higher. Descriptive statistics were used to describe the samples and comparisons between groups were done using Student's t-test, Pearson chisquare, Fisher exact, and multiple logistic regression as appropriate. The significance level for all statistical tests was set at p < 0.05.

#### Chapter 4 Results

#### 4.1 Utilization of cardiovascular services for CAD

From 1998 to 2007, the number of cardiac catheterization procedures increased by 32%, whereas the number referred for revascularization increased by 8%.

In the five years before the introduction of DES, the number of cardiac catheterization procedures increased from 2196 in 1998/1999 to 2528 in 2002/2003, an increase of 15.1% (Table 3). This coincided with an increase in the number of CABGs performed from 437 in 1998/1999 to 568 in 2002/2003, an increase of 30%. In the five years following the introduction of DES, the number of cardiac catheterization procedures increased from 2844 in 2003 to 2903 in 2007, an increase of 2.1%. The number of CABGs performed annually fell from 565 in 2003 to 492 in 2007, a decrease of 12.9%, and the annual number of PCI increased from 709 in 2003 to 766 in 2007, an increase of 8%.

In the year prior to the introduction of DES, 50% of those referred for revascularization were treated with PCI, compared to 59% in 2007. The annual number of patients who received DES increased from 89 in 2003 to 435 in 2007, an increase of 389% (Table 3). Within one year of the introduction of DES, half of all stents inserted comprised DES. There is overlap of the data in the year prior to (2002/2003) and the year following (2003) the introduction of DES. Since this study is examining 5-year trends and not changes from year to year, this is not a significant limitation of the data.

	Prior to introduction of DES			Following the introduction of DES				DES		
	1998/ 1999	1999/ 2000	2000/ 2001	2001/ 2002	2002/ 2003	2003	2004	2005	2006	2007
Cardiac catheterization	2196	2269	2258	2389	2528	2844	2722	2801	2949	2903
Referred for CABG	578	613	628	717	654	677	665	552	588	543
Number of PCI performed	631	536	529	550	659	709	635	668	826	766
Number of DES used		-	-	-	-	89	311	419	509	435
% PCI receiving DES	-	-	-	-	-	13	50	63	64	60
Total revasc	1209	1149	1157	1267	1313	1386	1300	1220	1414	1309
% CABG of total revase.	48	53	54	57	50	49	51	45	42	41
CABG performed	437	473	641	626	568	565	550	533	490	492
CABG wait list	227	308	223	243	222	218	260	271	88*	78

# Table 3: Annual utilization of cardiovascular services in NL from 1998 to 2007

\*Wait list reassessed

## 4.2 Clinical Characteristics

The clinical characteristics of patients who had a cardiac catheterization can be seen in Table 4. Data seen in the tables may not always add up to the total number of patients shown in the table as there was missing data in some categories. This will be addressed in the limitations. The total number of diagnostic cardiac catheterizations that were performed from April 1, 2005 to September 30, 2005 was 1341. 65.5% of the patients who had a cardiac catheterization were males. The mean age in years was 60.8 with a standard deviation of 10.8. No published age or gender data was available for patients who had cardiac catheterization in 1998/1999. Chi square test was used to compare clinical characteristics of patients from 1998/1999 to 2005. Statistically significant changes were noted for indications for cardiac catheterization. When comparing the proportions of patients in each year it can be seen that unstable angina decreased by 17.2%, while MI/post MI angina, chest pain of uncertain origin and other indications increased by 7.6%, 3.8% and 5.6%, respectively. Patients having an ejection fraction < 35% had a small decrease of 2.3%. The number of patients on maximal medical therapy had a very significant drop from 70.9% to 28%. Out of the 1341 patient who had cardiac catheterization in 2005, 46.7% had missing data for the maximal medical therapy category due to limitations in data collection methods (Data not shown). Patients who had a very positive stress test had a decrease of 4% from 1998/1999 to 2005. Significant changes were seen in coronary anatomy from 1998/1999 to 2005. There was an increase in left main disease (2%), double vessel disease without PLAD (3.3%) and single vessel disease without PLAD (4.3%). Decreases were seen in triple vessel disease (9.3%).

	1998/1999	2005			
	12 months	6 months			
	(N=2071)	(N=1341)			
	Mean (SD)	Mean (SD)			
Age, years	-	60.8 (±10.8)	-	-	-
	N (%)	N (%)	X <sup>2</sup>	df	p-value
Male	-	879 (65.5)	-	-	-
Indication for CC			147.0	4	0.000
Stable angina	673 (32.5)	434 (32.4)			
Unstable angina	761 (36.7)	262 (19.5)			
MI/Post MI angina	372 (18.0)	343 (25.6)			
Chest pain of uncertain origin	96 (4.6)	113 (8.4)			
Other	169 (8.2)	185 (13.8)			
Ejection Fraction < 35%	256 (12.4)	127 (9.5)	6.83	1	0.009
Maximal medical therapy	1468 (70.9)	376 (28.0)	601.60	1	0.000
Very positive stress test	366 (17.7)	177 (13.2)	12.17	1	0.000
Coronary Anatomy			78.0	5	0.000
Left Main	114 (5.5)	101 (7.5)			
Triple vessel	531 (25.6)	219 (16.3)			
Double vessel with PLAD	161 (7.8)	58 (4.3)			
Double vessel without PLAD	257 (12.4)	211 (15.7)			
Single vessel with PLAD	150 (7.2)	55 (4.1)			
Single vessel without PLAD	340 (16.4)	278 (20.7)			
No critical CAD	516 (24.9)	410 (30.6)	13.18	1	0.000

# Table 4: Clinical characteristics of patients who had cardiac catheterization in 1998/1999 and 2005

CC - Cardiac Catheterization

double vessel disease with PLAD (3.5%) and single vessel disease with PLAD (3.1%). The number of patients without critical CAD increased by 5.7%.

The clinical characteristics of patients diagnosed by cardiac catheterization with critical coronary artery disease are listed in Table 5. The number of patients who were diagnosed with critical CAD after cardiac catheterization was 927 or 69%. Data was not available for diabetes mellitus or maximal medical therapy in 1998/1999. Using Student's t-test to compare means of age from 1998/1999 to 2005, it is shown that the means are significantly different. When comparing the data from 2005 with that of 1998/1999, it can be seen that the characteristics gender, very positive stress test and EF <35% do not differ significantly. There is no data from 1998/1999 regarding the number of patients with diabetes mellitus but 32% of patients in 2005 had diabetes at the time they were diagnosed with critical CAD. A significant change in angina class was shown. Patients with class I to II angina increased by 12.4% and those with class III angina decreased by 11.4%. The proportion of patients who did not have angina or whose angina status was uncertain and those with class IV angina did not change much between 1998/1999 to 2005. No data is available for maximal medical therapy in 1998/1999 for comparison to 2005. Significant changes in coronary anatomy were seen. Left main disease increased by 3.9%, triple vessel disease decreased by 11.4% and single vessel disease increased by 4.9%. Recommendations for treatment changed significantly from 1998/1999 to 2005. CABG decreased by 5.4%, PCI decreased by 5%, medical management increased by 8% and other management (i.e., heart transplant, implantable cardioverter-defibrillator) increased by 1.6%.

### Table 5: Clinical characteristics of patients diagnosed by cardiac catheterization with critical coronary artery disease in 1998/1999 and 2005

	1998/1999 2005				
	(N=1625)	(N=927)	t-test		p-value
	Mean (SD)	Mean (SD)			
Age, years	60 (±11)	62 (±10)	-4.6838		0.000
	N (%)	N (%)	X <sup>2</sup>	df	p-value
Male	1152 (71)	674 (72.7)	0.96	1	0.327
Diabetes mellitus	-	297 (32.0)	-	-	-
Angina class			98.6	3	0.000
No angina/uncertain	117 (7)	57 (6.1)			
Class I to II	131 (8)	189 (20.4)			
Class III	534 (33)	200 (21.6)			
Class IV	843 (52)	481 (51.9)			
Very positive stress test	326 (20)	177 (19.1)	0.35	1	0.554
Ejection fraction <35%	226 (14)	127 (13.7)	0.02	1	0.888
Maximal medical therapy	-	376 (40.6)	-	-	-
Coronary anatomy			39.1	3	0.000
Left main	119 (7)	101 (10.9)			
Triple vessel	568 (35)	219 (23.6)			
Double vessel	438 (27)	269 (29.1)			
Single vessel	500 (31)	333 (35.9)			
Recommendation for Treatment			30.3	3	0.000
CABG	578 (36)	284 (30.6)			
PCI	631 (39)	315 (34.0)			
Medical	397 (24)	297 (32.0)			
Other	16(1)	24 (2.6)			

#### 4.3 Clinical factors influencing management strategy of critical CAD

In 2005, 284 patients with critical CAD were referred for CABG. The clinical characteristics of those patients are shown in Table 6. Characteristics that did not significantly change from 1998/1999 to 2005 are age, gender, very positive stress test and EF < 35%. Angina class changed significantly. Class III angina decreased by 7.4%, class IVa angina increased by 7.3% and class IVb or c angina decreased by 24.4%. The number of patients diagnosed with critical CAD who were on maximal medical therapy decreased significantly from 1998/1999 to 2005 by 35.5%. A significant change in the coronary anatomy category was seen with increases in left main disease (8%), double vessel disease without PLAD (5.7%) and single vessel disease without PLAD (4.3%). There was a decrease in triple vessel disease of 15.3%. In 1998/1999 and 2005, the majority of patients referred for surgery had either triple vessel disease or left main CAD (69.7% in 2005 and 77% in 1998/1999), and a smaller proportion had single or double vessel disease without PLAD (1% in 2005 and 9% in 1998/1999). This is consistent with more severe disease being treated with CABG.

Two hundred and eighty four (30.6%) were referred for CABG and 315 (34%) for PCI in 6 months of 2005 compared to 578 (36%) and 631 (39%) respectively in 12 months of 1998/1999 (Table 5). The elinical characteristics of patients diagnosed with critical CAD by management strategy are presented in Table 7. CABG and PCI were combined to form a revascularization strategy. In subgroup categories such as angina class and

	1998/1999 (N=578)	2005 (N=284)	t-test		p-value
	Mean (SD)	Mean (SD)			
Age, years	62 (±9)	63 (±9)	1.533		0.126
	N (%)	N (%)	X <sup>2</sup>	df	p-value
Male	445 (77)	227 (79.9)	0.96	1	0.327
Angina Class			50.3	3	0.000
No, I or II	67 (12)	44 (15.5)			
III	248 (43)	101 (35.6)			
IVa	24 (4)	32 (11.3)			
IVb or c	239 (41)	47 (16.6)			
Very positive stress test	154 (27)	75 (26.4)	0.01	1	0.920
Ejection fraction <35%	90 (16)	39 (13.7)	0.51	1	0.475
Maximal medical therapy	439 (76)	115 (40.5)	104.26	1	0.000
Coronary anatomy			36.9	5	0.000
Left Main	97 (17)	71 (25)			
Triple vessel	348 (60)	127 (44.7)			
Double vessel with PLAD	71 (12)	23 (8.1)			
Double vessel without PLAD	39 (7)	36 (12.7)			
Single vessel with PLAD	11 (2)	9 (3.2)			
Single vessel without PLAD	12 (2)	18 (6.3)			

# Table 6: Clinical characteristics of patients referred for CABG in 1998/1999 and 2005

	Medical	Revascularization			
	Management	CABG/PCI			p-
	N=297	N=599	t-test		value
	Mean (SD)	Mean (SD)			
Age, years	63 (±11)	62 (±10)	1.3625		0.173
	N (%)	N (%)	X <sup>2</sup>	df	p- value
M	101 ((4)	450 (77)	16.12		0.000
Male	191 (64)	459 (77)	15.13	1	0.000
Age > /5	37(12)	60 (10)	1.23	1	0.267
Diabetic	90 (30)	200 (33)	0.86	1	0.353
Angina Class			31.7	2	0.000
None, I, II	89 (30)	85 (14)			
III	47 (16)	148 (25)			
IV	138 (47)	290 (48)			
Very positive stress test	40 (14)	134 (22)	10.06	1	0.002
Ejection Fraction < 35%	41 (14)	71 (12)	0.69	1	0.406
Maximal medical therapy	105 (35)	260 (43)	5.33	1	0.021
Coronary Anatomy			59.6	5	0.000
Left main	18 (6)	82 (14)			
Triple vessel	48 (16)	163 (27)			
Double vessel with PLAD	11 (4)	44 (7)			
Double vessel					
without	76 (26)	129 (22)			
PLAD					
Single vessel with PLAD	11 (4)	43 (7)			
Single vessel without PLAD	130 (44)	137 (23)			

# Table 7: Clinical characteristics of patients with critical coronary artery disease by management strategy in 2005

coronary anatomy, only proportions of patients from 1998/1999 to 2005 were compared. No statistical analyses were performed for subgroups. Factors associated with a revascularization management strategy rather than medical management included male gender, angina class III, presence of a very positive stress test, on maximal medical therapy and extent of CAD (left main, triple vessel, double vessel and single vessel with PLAD). Factors associated with medical management rather than a revascularization strategy included no angina or CCS angina class I to II and single vessel disease without PLAD.

Table 8 shows the clinical characteristics of patients with critical coronary artery disease by revascularization strategy in 2005. Factors associated with CABG rather than PCI included diabetes, CCS angina class III, presence of a very positive stress test and extent of CAD (left main and triple vessel disease). Factors associated with PCI rather than CABG included higher CCS angina class (Class IV) and less severe CAD (double vessel without PLAD and single vessel disease).

Multiple logistic regression was carried out using all the clinical variables collected. Univariate comparison of factors is not provided in the thesis. Covariates were not forced. The independent predictive factor identified by multiple logistic regression, for revascularization rather than medical management was male gender (OR 1.75, CI 1.23-2.51) (Table 9a). Angina class 0-2 (OR 0.38, CI 0.25-0.57) and single or 2 vessel disease (OR 0.41, CI 0.28-0.6.) were less likely to be associated with a revascularization strategy rather than medical therapy. A very positive stress test (OR 1.57, CI 1.00-2.45)

	CABG N=284	PCI N=315	t-test		p-value
	Mean (SD)	Mean (SD)			
Age, years	63 (±9)	61 (±11)	2.4196		0.016
	N (%)	N ( %)	X <sup>2</sup>	df	p-value
Male	227 (78)	232 (74)	3.29	1	0.070
Age > 75	33 (13)	27 (9)	1.54	1	0.215
Diabetic	108 (38)	92 (29)	5.23	1	0.022
Angina Class			70.6	2	0.000
None, I, II	44 (15)	41 (13)			
III	101 (45)	47 (14.9)			
IV	79 (35)	211 (67)			
Very positive stress test	75 (27)	59 (19)	5.07	1	0.024
Ejection Fraction < 35%	39 (14)	32 (10)	1.83	1	0.176
Maximal medical therapy	115 (55)	145 (46)	1.87	1	0.171
Coronary Anatomy			206	5	0.000
Left main	71 (25)	11 (4)			
Triple vessel	126 (45)	37 (12)			
Double vessel with PLAD	23 (8)	21 (7)			
Double vessel without PLAD	36 (13)	93 (30)			
Single vessel with PLAD	9 (3)	34 (11)			
Single vessel without PLAD	18 (6)	119 (38)			

# Table 8: Clinical characteristics of patients with critical coronary artery disease by revascularization strategy in 2005

Table 9: Independent predictive factors for (A) coronary revascularization rather than medical therapy and (B) for CABG rather than PCI in the treatment of critical coronary artery disease

	Odds ratio*	95% CI
Male	1.75	1.23 - 2.51
Angina class 0-2 <sup>+</sup>	0.38	0.25 - 0.57
Very positive stress test	1.57	1.00 - 2.45
Single or double vessel disease	0.41	0.28 - 0.60
Age > 75 years	0.59	0.34 - 1.01

## (A) Revascularization v medical management

\*Multiple logistic model also included diabetes, class 3 angina, maximal medical therapy and ejection fraction < 35% none of which approached statistical significance. + reference: unstable angina

	(b) chibd ( i ci					
	Odds ratio*	95% CI				
Angina class 0-2 <sup>+</sup>	2.44	1.29-4.60				
Class 3 <sup>+</sup> angina <sup>+</sup>	4.64	2.69-8.00				
1 or 2 vessel disease	0.07	0.04-0.11				

(B) CABG v PCI

Multiple logistic model also included Age > 75 yrs, gender, diabetes, very positive stress test, ejection fraction < 35% and maximal medical therapy none of which approach statistical significance.

+ reference unstable angina

and age >75 approached statistical significance (OR 0.59, CI 0.34-1.01) but because the confidence interval included 1, it cannot be said that they are statistically significant. Multiple logistic regression identified that the independent predictor for CABG rather than PCI was stable angina (angina classes 0-3) while single and double vessel disease were less likely associated with CABG rather than PCI (Table 9b).

## 4.4 CABG wait times by priority group

Urgency rating scores for CABG, calculated using definitions from Naylor, were used to assign priority ratings and recommended waiting times to patients referred for CABG in 1998/1999 and 2005 (77). The results can be seen in Table 10. The results show that there has been improvement in reaching recommended waiting times since 1998/1999. All priority groups show an increase in the number of patients who have their CABG within the recommended waiting time. Compared to 1998/1999, the percentage of patients receiving their CABG within the recommended maximum wait time increased by 110% for very urgent patients, 50% for urgent patients, 90% for semi-urgent patients, 14% for short wait patients and 131% for delayed wait patients. In those classified as urgent or very urgent, 45% had CABG within the recommended wait time in 2005 compared to 29% in 1998/1999, and in those classified as semi-urgent or short wait, 87% had CABG within the recommended wait time in 2005 compared to 59% in 1998/1999. There is no data from 1998/1999 regarding marked delay patients to compare to the 2005 data. The number of patients who had their CABG on time in the marked delay priority group in 2005 was 78%, which is relatively high compared to the other priority groups.

			1998/1999 2005 (N=493) (N=284)		2005 (N=284)			
Priority	Recommended maximum waiting time	Total (N)	Target (N)	Target (%)	Total (N)	Target (N)	Target (%)	% Change
Very Urgent	<24h	24	5	21	18	8	44	110
Urgent	< 72h	141	42	30	40	18	45	50
Semi-urgent	< 2 weeks	68	33	49	35	32	93	90
Short Wait	< 6 weeks	59	42	71	37	30	81	14
Delayed wait	< 3 months	210	71	35	145	117	81	131
Marked Delay	< 6 months	-	-	-	69	54	78	-

# Table 10: Waiting times of patients referred for CABG in 1998/1999 and 2005 by priority and recommended maximum waiting time

## 4.5 Coronary stent utilization

Drug-cluting stents were first used in NL in May 2003. Table 11 shows PCI and stent utilization data since the introduction of DES from 2002/2003 to 2007/2008. During this time period, the number of patient who had PCI and the number of patients who received stents had slight increases of 8%. The total number of stents used was higher than the number of patients receiving stents indicating that many patients received more than one stent during their PCI procedure.

The number of BMS used declined by 51% from 2003/2004 to 2007/2008. The year after DES were introduced there was a drop in BMS use of 46%. The number of DES used has risen by 518% since their introduction to 2007/2008. The number of patients receiving DES has risen by 389% during this same time period. As with total stents, the number of DES used is higher than the number of patients receiving stents. This indicates that many patients are receiving multiple DES. The percent of stent cases receiving DES has risen by 47%.

	2002/ 2003	2003/ 2004	2004/ 2005	2005/ 2006	2006/ 2007	2007/ 2008	% Change (2003/2004 to 2007/2008)
Total PCI completed	659	709	635	668	826	766	8
# Patients Receiving stents	N/A	671	624	659	791	727	8
Total stents used	N/A	1068	901	1021	1260	1131	6
# BMS used	N/A	962	516	463	514	476	-51
# DES used	N/A	106	385	559	746	655	518
# Pts receiving DES	N/A	89*	311	419	509	435	389
% of stent cases receiving DES	N/A	13.3%	50%	63%	64%	60%	47

# Table 11: PCI and stent utilization data for 2002/2003 to 2007/2008

\*DES usage beginning May 2003

### Chapter 5 Discussion

#### 5.1 Cardiac catheterization utilization

The data shows that between 1998/1999 to 2005 the number of cardiac catheterizations increased by 28%. Similar results were seen in Alberta and British Columbia from 2000 to 2004 (93). That means that referrals for catheterizations must have also increased during this period of time. The increased utilization of catheterizations in 2005 compared to 1998/1999 was attributable to a growth in the number of patients being investigated for Ml/post MI angina, chest pain of uncertain etiology and other various indications (i.e. CHF). One possible reason for this increase in investigations is related to the aging population of Newfoundland. The average age of people receiving catheterizations in 2005 was 60.8±10.8 and the age group from 50 to 69 years old for the population of Newfoundland has increased by 61.3% from 1996 to 2006 (94). Therefore more catheterizations would be expected for this growing age group.

The proportion of patients who were diagnosed with critical CAD by cardiac catheterization has decreased by 9% since 1998/1999. This is unexpected but may reflect the increased number of patients being investigated for symptoms not necessarily caused by CAD.

## 5.2 Management strategies

The proportions of patients with critical CAD referred for different treatment options including medical management, PCI, CABG or other, changed significantly from 1998/1999 to 2005. Medical management increased by 8%. PCI decreased by 5%. CABG decreased by 5.4% and other increased by 1.6%. In 1998/1999 PCI was the most common treatment option at 39% followed by CABG at 36% and medical management at 24%. In 2005, PCI was still the most common at 34% but medical management was more common than CABG (32% vs. 30.6%). Therefore, it appears that the increased numbers of patients diagnosed with critical CAD in 2005 were managed by medical therapy rather than revascularization. This supports the previous statement that more patients are being placed on medications to reduce the risk of cardiovascular events and therefore fewer patients require more invasive procedures like CABG or PCI. Patients with more severe CAD disease (left main, triple vessel, double vessel with PLAD and single vessel with PLAD) were referred for revascularization rather than medical management. Those patients were also more likely to have a very positive stress test and be on maximal medical therapy. This is expected as a very positive stress test has been correlated with more severe CAD and based on the CCS guidelines these patients should be on maximal medical therapy (95, 96).

Referrals for CABG surgery were more likely if the patient had more severe disease or was diabetic. Multiple studies have shown that CABG has better outcomes, including less mortality and fewer major adverse cardiac events, in patients with multivessel and left main disease compared to PCI (97, 98, 99, 100, 101, 12, 103). Similar results were seen in patients with diabetes (97, 99, 100, 101, 104). More patients with higher angina class were referred for PCI than CABG, however, those referred for PCI had less severe disease.

Since DESs were introduced in 2003, the total number of PCIs has increased as well as the number of patients receiving stents. Total stent use has remained the same with an increase in DES use and a decrease in BMS use. In 2007/2008, 60% of stent cases received DES compared to 13.3% in 2003/2004. CABG numbers have decreased at the time when DES utilization has increased.

#### 5.3 Decreased CABG utilization

Coronary revascularization procedures for critical CAD are rapidly evolving. Rapid incorporation of DES has occurred both in the USA (90) and in Canada (3) since their approval. In NL, this rapid introduction has reduced the use of CABG and solved a major health care delivery problem. Prior to the introduction of DES in 2003, there was a very long waiting list causing long wait times for CABG. There was a need to increase the number of CABGs that were performed. Introduction of DES has been associated with partial substitution of BMS with DES and an increased use of PCI, especially in those with unstable angina. This occurred at a time when cardiac catheterization utilization continued to increase and use of CABG in patients with stable angina continued to grow.

Planning cardiac services in an era of rapid change is difficult but benchmarking the provision of CABG is important (91). Previous recommendations for increased CABG use in NL were based on the demonstration that referrals from cardiology were appropriate, that a growth in necessary CABGs would continue, and that consistent indications for CABG use would persist (14, 16). The predictions for the number of CABGs have proven to be too high since the introduction of DES. Fortunately, the introduction of DES occurred before resources, such as more operating rooms, surgeons, perflusionists, anesthetists, and intensive care units, were provided to perform a higher number of CABGs. However, there needs to be a constant evaluation of need and utilization in order to provide an appropriate match between supply and demand of cardiac services.

Current predictions of future DES utilization are based on the belief that DES relieve obstructive coronary disease, provide durable mechanical results and do more good than harm (90). However, there are some concerns as to whether DESs are safe in the long term (2, 92). If these concerns prove to be true then DES utilization will decrease and either BMS utilization may increase, CABG utilization may increase or a combination of both may occur.

#### 5.4 Wait Times for CABG

Wait times decreases have been reported for both CABG and PCI in other provinces in Canada since the introduction of DES (93). Management of CAD in the twenty-first

century has changed rapidly in that DESs are being substituted for the more invasive CABG surgery. The rapid incorporation of DES in practice has alleviated the problem of large CABG waitlists. Over five years, the number of CABGs performed decreased from 565 to 492, and the waiting list from 218 to 78. This is as expected as DES use increased and the backlog of patients waiting for CABG was dealt with in the few years following the introduction of DES in 2003.

The target RMWT for CABG is being reached for most patients in the semi-urgent (93% in 2005 vs 49% in 1998/1999), short wait (81% in 2005 vs 71% in 1998/1999), and delayed wait (81% in 2005 vs 35% in 1998/1999) priority groups. For very urgent (44% in 2005 vs 21% in 1998/1999) and urgent (45% in 2005 vs 30% in 1998/1999) patients, the target RMWT is still relatively low and, along with the short wait priority group, have had only a moderate increase since 1998/1999. This shows that improvements are being made but more work still needs to be done to increase access for the very urgent and urgent priority groups. The very urgent and urgent groups have the sickest patients who need CABG within a short period of time. These patients are the ones who should be getting CABG within the recommended wait time but that target is still not being reached. Some hypotheses as to why this is occurring are that there is not enough staff including doctors and nurses to accommodate these people in such a short period of time. There may also be problems in getting time in the operating room on short notice so patients may be bumped until an operating room becomes available. Since these patients require urgent CABGs they may become unstable and may have to wait before they have their surgery until they have stabilized.

As a result of the First Minister's Meeting in 2004, three budget programs were set up in 2007 to support patient wait times guarantees. In 2007, NL decided to focus on coronary artery bypass grafting surgery in order to obtain funding through the Patient Wait Time Guarantee Trust Fund (\$612 million nationally, of which Newfoundland and Labrador will receive \$18 million) and be able to access funding through Canada Health Infoway (\$400 million nationally) for the development of health information technology, such as electronic health records and wait time information systems (21). As well, the Patient Wait Times Guarantee Pilot Fund added an additional \$30 million, which has been set aside for provinces to undertake relevant, innovative pilot projects designed to help implement their guarantees.

#### Chapter 6 Summary

### 6.1 Conclusions

The purpose of this study was to determine how referral patterns for coronary revascularization have changed and how this impacted waiting times for CABG. The clinical characteristics of patients who underwent a diagnostic cardiac catheterization from April 1, 2005 to September 30, 2005 were determined using data from various sources including Meditech, chart reviews and the cardiac catheterization lab data. This study showed that there has been an increase in cardiac catheterizations since 1998/1999. This increase is attributable to a growth in the number of patients being investigated for stable angina, MI, and chest pain of uncertain etiology. The proportion of patients who had critical coronary artery disease was also determined by data from the above sources. There has been a change in the proportion of patients diagnosed with critical CAD from 1998/1999 to 2005 from 78% to 69%, respectively. While more cardiac catheterizations are being done, less critical CAD is being detected. This is in contrast to other centers in Alberta and British Columbia where more catheterizations are being done but severity of patient illness is increasing (93). Results from a US study also show an increase in cardiac catheterizations during this time period, but again, report that there was an increase in critical disease (105).

The referral patterns for those patients diagnosed with critical CAD has also changed. The possible treatment recommendations include CABG, PCI, and medical management. Referrals for CABG have decreased while there has been an increase in medical management. Even though referrals for PCI have remained the same, there has been an increase in the number of PCIs being performed and an increase in the number of people receiving stents.

DES use has increased dramatically since its introduction in 2003 and this is directly related to the decrease in CABG referrals. Introduction of DES has been associated with partial substitution of BMS with DES and an increased use of PCI, especially in those with unstable angina. This change in management of critical CAD has significantly decreased the size of the CABG waitlist in NL and therefore decreased the need for more resources related to CABG utilization to be put in place in NL. DESs are a far less invasive procedure than CABG and there are fewer risks associated with their use. However, since DESs are a relatively new procedure more research needs to be done to ensure their safety and efficacy over the long term. If DESs are proven to be safe and effective over the long term then a trend towards fewer referrals for CABG and more referrals for PCI should continue. However, there needs to be constant evaluation of supply and demand for CABG and DES utilization.

Urgency rating scores (URS) were calculated using the Cardiac Care Network of Ontario URS Calculator (89). These scores were used to determine the patient's priority grouping. The actual waiting times for the patient were observed and the recommended maximum wait times (RMWT) were calculated. The RMWT for CABG is being reached for most patients in the semi-urgent, short wait, delayed wait, and marked delay priority groups. For very urgent and urgent patient priority groups, the RMWT is still relatively

low and, along with the short wait priority group, has not changed significantly since 1998/1999. More work still needs to be done to increase the very urgent and urgent priority groups. More human resources, including doctors, nurses, and staff, and increased operating room time could help increase the number of patients who reach the target RMWT for these groups. Increased funding would be required to achieve this.

## 6.2 Limitations

There are several limitations to this study. One of the major limitations is the fact that the data for this study was taken over a period of 6 months in 2005 while the data to which it is being compared came from a one year period. It is possible that the six months used in this study is not representative of the entire year. Also, the one year period used is the fiscal year 1998/1999. Since this overlaps calendar years, utilization data (Table 3) has overlapping data in 2002/2003 and 2003. Due to different data collection methods for the five years prior to and following DES introduction, they were unable to be separated to determine actual change in utilization for those years. As this was a retrospective study, there was no way to prove the accuracy of the data collection. As well there was no way to recover missing data. Data was collected from three different sources, the cardiac catheterization lab reports, Meditech, and hospital charts. Some required data could not be found in any of the three sources while other data was contradictory. In cases where there was a contradiction, data was abstracted in consultation with a cardiologist. The accuracy of the data from each source was unknown. Data that was particularly hard to obtain was maximal medical therapy as medications taken before the patient's cardiac

catheterization were not always available. Therefore, much of this information was missing and the results may not be accurate. Raw data for 1998/1999 was not available so when the actual number was not available, a comparison to data from 2005 could not be performed. A limitation in the statistical analysis of the study was the analysis of the waiting times of patients referred for CABG. Some of the categories, especially the very urgent, urgent, and semi-urgent priority groups had very small numbers of patients. This may have skewed the data.

#### 6.3 Future research and health policy implications

Future research needs to be done to determine whether the change in CABG wait times is permanent due to ongoing changes in referral patterns. In future studies on wait times for CABG surgery, data on vessel disease and other comorbidities such as valvular disease, LV function, and renal disease needs to be captured as these can have an impact on which management strategy is used (24, 33, 36, 50). Other data that has been shown to have an impact on management strategy are previous revascularization, current medical therapies, type of MI and smoking status (55, 56, 79). DESs have become increasingly utilized over CABG surgery since their introduction. However, the long term safety of DES needs to be established. The type and number of stents placed is important for future studies as DES tend to be used in more complex disease as compared to BMS. Rates of restenosis and in stent thrombosis, as well as other outcomes of critical CAD, including MI, stroke, and death should be used to assess safety of DES versus CABG and medical management. Both short term and long term data is required. Medical management for

critical CAD is also increasing. Data regarding specific medications patients are taking needs to be captured in the data analysis. These include antiplatelet agents, beta-blockers, inhibitors of the renin-angiotensin system and statins or other lipid-lowering agents. This data can be used to determine whether the patient is on maximal medical therapy at their time of diagnosis of critical CAD and how this impacts referrals and waiting times for CABG. Further research is needed to determine why the wait times for very urgent, urgent and short wait patient priority groups are still higher than the RMWT and how this can be improved.

Wait list management is an important part of reducing wait times for CABG. Continual monitoring of wait lists should be done to remove patients from the list if they die, move away, decline the operation, accept surgery from another surgeon or switch to medical management (106). Wait list management is a growing area of research and is needed to determine the most efficient ways to maintain wait lists. Demand for CABG surgery needs to be evaluated on a regular basis as technologies for management of cardiovascular disease are changing rapidly. As well, new medical therapies are developed rapidly and population lifestyles are changing. As demand for CABG changes, so does supply. Human resources, infrastructure such as equipment and operating time, system management, and coordination of services need to be taken into consideration when assessing supply. Continued funding of patient wait time guarantees by the government and continual reassessment of supply and demand for CABG will help to ensure optimal patient wait times in this era of rapid change in management of critical CAD.

Benchmarking the number of coronary revascularization procedures that should be funded each year is important. As referrals for these procedures have been demonstrated to be appropriate by a previous study, the number needed to be funded can be derived from the number funded in the previous year (14). However, we have shown that new intervention strategies may rapidly change the number of CABGs needed and therefore the amount of funding will change. Consequently, benchmarking the number of revascularization procedures that require funding should be reviewed annually.

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## Appendix A

## **Chart Audit Form**

		Chart Audit Form	
	Changes in R	eferral Patterns for Coronary	Revascularization:
	The Impac	t on Coronary Artery Bypass (	Grafting Surgery
Case Numb	er:		
Gender:	1. Male	2. Female	Age:
Indication f	or Heart Cathe	terization: 1. Stable Angina 2. Unstable Angina 3. Myocardial Infarct 4. Post MI Angina 5. Chest Pain of unce 6. CHF 7. Other, specify	ion rtain origin
Date of Dia	gnostic Heart (	Catheterization: DMY	
Critical Cor	onary Artery I	Disease (CAD): 1. Yes**	2. No

#### \*\*If critical CAD is yes, continue with data collection

- Coronary Anatomy: 1. Single vessel disease, no proximal LAD (PLAD) involvement
  - 2. Single vessel disease with PLAD involvement
  - 3. Double vessel disease, no PLAD involvement
  - 4. Double vessel disease with PLAD involvement
  - 5. Triple vessel disease
  - 6. Unprotected left main disease
  - 7. Protected left main disease

#### LV Angiogram: 1. Grade 1 ventricle

- 2. Grade 2 ventricle
- 3. Grade 3 ventricle
- 4. Grade 4 ventricle

Please give specific details of the lesion and the location of the lesion(s) (i.e. 80% mid RCA etc.)

If there is no data on the grade of the ventricle, please provide a general description of the ventricle (*i.e., generalized hypokinesis, or mild hypokinesis of the inferior wall etc.*)

Ejection Fraction < 35%:	1. Yes	2. No	Date: DMY	<u></u>
Diabetes:	1. Yes	2. No		
CCS Angina Class:	1. Class 1 to 2 2. Class 3 3. Class 4			
Very Positive Stress Test:	1. Yes	2. No		
Maximal Medical Therapy:	1. Yes	2. No		
Recommendations for Treatn	nent: 1. Mec 2. PCI 3. CAI 4. Oth	lical Managem 3G er, specify	ent	

#### If the patient was referred for CABG complete the following:

 Date accepted for CABG:
 D\_\_\_\_M\_\_Y\_\_\_

 Date of CABG:
 D\_\_\_\_M\_\_Y

Number of days awaiting CABG:

In order to calculate the Urgency Rating Score (URS) for CABG complete the following, as per URS Calculator instructions:

A. Canadian Cardiovascular Society Angina Class:

- 1. Class 1 or 2
- 2. Class 3
- 3. Class 4A
- 4. Class 4B
- 5. Class 4C

в.	vessei	1. Left Main ≥ 50% stenosis	1. Yes	2. No
	]	<ol> <li>If PLAD has &gt; 70% stenosis and if there is &gt; 70% stenosis <u>in at least one</u> of the following: distal LAD, Circumflex, RCA.</li> </ol>	1. Yes	2. No
		3. If PLAD $>70\%$ and no other artery $>70\%$	1. Yes	2. No
		<ol> <li>If PLAD does not have &gt; 70% stenosis or is blan is there &gt;70% stenosis <i>in all three</i> of distal LAD Circumflex, or RCA?</li> <li>There is not &gt; 70% stenosis <i>in all three</i> of the</li> </ol>	k; 1. Yes	2. No
		above arteries (Distal RCA, Circ, RCA) i.e. at least one vessel < 70%	1. Yes	2. No
С. П	Left V	entricular Function 1. $EF \ge 50\%$ or unknown 2. $EF \ge 35\%$ and $< 50\%$ 3. $EF \ge 20\%$ and $< 35\%$ 4. $EF < 20\%$	1. Yes 1. Yes 1. Yes 1. Yes	2. No 2. No 2. No 2. No
		EF obtained via: 1. ECHO 2. MUGA 3. Cat Date obtained: DMY	h	
D. 1	lscher	nic Risk	1. High	2. Low
	]	<ol> <li>High ti:</li> <li>2.5 mm ST depression</li> <li>ST elevation &gt; 1 mm in leads without q waves</li> <li>Low work loads (heart rate &lt; 120)</li> <li>Early onset ST segments in 1<sup>st</sup> stage (3 min)</li> <li>ST segment depression lasting longer than 8 minutes into recovery stage</li> <li>Maximum heart rate &lt; 120 on cardio-inhibitory medication</li> <li>SBO lowerd at least by 10 mmHg</li> <li>≥ 3 beats of ventricular tachycardia</li> <li>New resting changes and/or reversible changes with pain</li> <li>High thallium: Suggest either anterior wall or multiple areas of myocardia to be in ischemic jeopardy</li> <li>High haller monitor: For ambulatory ECG monitoring, shows prolonged and unequivocal ischemia</li> </ol>		

### 

- 2. Low if:
  - Minor or no convincing findings for ischemia on exercise, ECG, Holter monitor, or radionucleotide scanning

E. Co-Morbidity		
1. Dialysis	1. Yes	2. No
2. Diabetes	1. Yes	2. No
3. CVD	1. Yes	2. No
4. CVA	1. Yes	2. No
5. COPD	1. Yes	2. No
6. CHF	1. Yes	2. No
F. Recent Myocardial Infarction		
MI within 30 days of acceptance to surgery	1. Yes	2. No
G. Previous CABG Surgery	1. Yes	2. No

To determine the patient's Urgency Rating Score, add the values in the boxes A through G. Enter that number here:

#### Recommended Maximum Wait Time (RMWT)

To determine the RMWT, take the URS value that was calculated above, and apply to the appropriate section below.

If the URS is	Use the following equation to calculate RMWT
>= 1.01 and <= 2	$RMWT = [(URS - 1)^* 1] + 0$
>= 2.01 and <= 3	$RMWT = [(URS - 2)^* 2] + 1$
>= 3.01 and <= 4	$RMWT = [(URS - 3)^* 11] + 3$
>= 4.01 and <= 5	$RMWT = [(URS - 4)^* 28] + 14$
>= 5.01 and <= 6	$RMWT = [(URS - 5)^* 48] + 42$
>= 6.01 and <= 7	RMWT = [(URS - 6)*90] + 90
> 7.01	RMWT = 180

RMWT:

### If the patient was referred for PCI, complete the following:

1.	Coronary Stent	1. Yes	2. No
2.	Drug-Eluting Stent	1. Yes	2. No
3.	Indication for Drug-Eluting Stent:		

# Appendix B

# Abbreviations

#### Abbreviations (in alphabetical order)

BMS - Bare metal stent

CABG - Coronary artery bypass grafting

CAD - Coronary artery disease

CC - Cardiac cathterization

CCS - Canadian Cardiovascular Society

CHF - Congestive heart failure

DES - Drug-eluting stent

EF - Ejection fraction

LAD - Left anterior descending artery

LMCA - Left main coronary artery

LV - Left ventricular

MI - Myocardial infarction

NL - Newfoundland and Labrador

PCI - Percutaneous coronary intervention

PLAD - proximal left anterior descending artery

PTCA - Percutaneous transluminal coronary angioplasty

RCA - Right coronary artery

RMWT - Recommended maximum wait time

STEMI - ST elevation myocardial infarction

URS - Urgency rating score







