BENCHMARKING THE PROVISION OF CORONARY ARTERY BYPASS GRAFTING SURGERY IN NEWFOUNDLAND AND LABRADOR

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Benchmarking the Provision of Coronary Artery Bypass Grafting Surgery in Newfoundland and Labrador

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Abstract

Governmental concern for the effective utilization of limited health care resources has necessitated the development of standardized, objective tools to measure and document changes within the health care system. The use of coronary artery bypass grafting surgery (CABGS), like all other health procedures, has high public cost and must be performed appropriately, when necessary, efficiently, and with high quality of care. Establishing the required frequency of a procedure, CABGS, in a population (benchmarking) is vital to ensure adequate allocation of resources. In 1995 researchers found that CABG surgery in Newfoundland and Labrador (NL) was being appropriately applied but that access to the service was far less than ideal. The authors benchmarked the need for CABGS. The current investigation was designed to reassess the need for CABGS in this province and to provide revised benchmarks. The analysis compared data between study periods and addressed the following areas: the current need for CABGS in NL, the appropriateness of utilization, the necessity of utilization, the waiting times, the quality of care delivered with this service, and the future need of CABGS in NL.

All patients identified with critical coronary artery disease (CAD) through coronary angiography (CA) between August 18, 1998 and August 13, 1999 were included in the study. In addition, all patients who received CABGS during the same study period were followed for quality of care. Findings were then compared with a previous study (1994/95).

In 1998/99, 1625 patients had critical coronary artery disease and were characterized by late stage angina symptoms and multi-vessel disease. The average age was 62 years and 75% were male. Four hundred thirty-four patients (434) underwent

CABGS during the study period while 517 patients were referred for surgery. Thus, the waitlist increased by ~ 30% throughout the year. Only 40% of patients received surgery within the recommended waiting time. Over 94% of the referrals were deemed necessary. There was an excellent correlation between the cardiovascular team and the objective RAND criterion in decision-making (Kappa=0.86). We identified an additional 91 patients for whom surgery was recommended, according to RAND criteria, but who did not receive a referral. Eighty-six percent (86%; n=78) of this group were actually treated with percutaneous transluminal coronary angioplasty (PTCA).

Since 1994/95, the number of diagnostic catheterizations has increased by 37%. In addition, there was a 50% increase in critical coronary artery disease diagnosis (1082-1625). In both studies, the proportion of patients with critical CAD diagnosed by angiography was similar. Although age and gender remained stable throughout the study periods, the latter (1999) cohort was characterized by a higher proportion of Class III angina, a lower proportion of positive exercise stress testing results, and less patients with a very low ejection fraction. Yet, the proportion of patients with critical CAD referred for CABGS remained stable (36%). Whilst there has been a dramatic increase in referrals for angioplasty (137%), there has been a relative decline in medical therapy as a means of treatment for these patients (-18%). Compared to 1995, increased utilization of CABGS was related to the diagnosis of patients at an earlier symptomatic phase of coronary artery disease (CAD) and to increased access to coronary catheterization. In addition, increased use of PTCA and changes in health care altered demand.

We concluded that physician clinical decision-making was an appropriate way by which to measure need for CABGS. The authors have noted an increase in utilization of

cardiac catheterization, which resulted in an increase in referrals for CABGS (8% per annum). Thus, allowing for growth in access to coronary angiography, and change in case mix as well as the need to reduce the waiting list, we estimated annual need to be 1.72 surgeries/ 1,000 population > 20 yrs of age in 2001/2002. However, predictions proved unreliable and need was underestimated.

In times of continual fluctuation in rate and changing assumptions between 1994 and 1999, it is difficult to provide a confident estimation of future need. Research should instead aim to identify stability. Persistent monitoring should recognize this period of stability and researchers will be better able to estimate future trends at that time.

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CHAPTER I

Introduction

1.1 CABGS in Newfoundland and Labrador

In the Canadian Health Care System, a third party, the Provincial Government, pays for services rendered to the population at large. Being a publicly funded system, its primary goal is to facilitate reasonable access and delivery of health services without incurring economic barriers to its citizens. Therefore an appropriate allotment of funding should be achieved via accurate and monitored establishment of the required frequency of procedures in the population (benchmarking data). The success of coronary bypass surgery in the management of symptomatic coronary artery disease has increased the demand for this revascularization technique. The health care system has failed to meet this demand. Gauging a community's need for CABG surgery should provide feedback to all parties involved and place necessary restraints on the provision of this service in the event of over utilization and increased funding, human resources, and technical support in the event of underutilization.

The province of Newfoundland and Labrador, like many other health care jurisdictions, is faced with widening gaps between the demands for health care and the ability to supply these resources (67). In times of fiscal restraint, there is need for the effective utilization of severely limited resources to protect patients, service providers, and the payer. Cardiac care places a substantial burden on the health care system with a provincial operating budget over $10 million (25). Each coronary artery bypass grafting (CABG) procedure costs between $11,000 and $34,000 (in 1988 Canadian dollars; with improved equipment, technological advances, and inflation, it is likely this figure has increased) (73,88,116,136). Unfortunately, Newfoundland

and Labrador has a high prevalence of coronary artery disease (CAD), with 82% of its people possessing at least one major risk factor, excluding family history (128).

In early 1990's, the wait-list for CABGS in NL was 18/100,000. There was higher output per surgeon as compared to the rest of Canada (24,25,58). Nevertheless, the wait list has continued to increase by approximately 20% per annum since that time (25). This excessive demand on resources was associated with difficulty in providing emergent care (84,105). Thus, in 1994/95 researchers sought to assess the Cardiac Care Program and found that despite CABGS being appropriately and necessarily applied, the access to this service was limited (42). At that time, the authors predicted the consequent need for CABGS and a substantial increase in funding for the cardiac program was approved.

Since that time, NL's Health Care Boards have been regionalized and efforts to expand the cardiac programs capacity have been implemented. However, indications for coronary revascularization have expanded, and changing fertility trends and mortality levels in Canada and NL alike have resulted in an age structure in which an increasing proportion of the population are elderly and at risk for CAD. Furthermore, the number of cardiac catheterizations performed has increased. This will also increase demand for CABGS (137). This is not surprising as angiography is the current means by which we can diagnose and hence, treat CAD. Historically, a ratio of 3.5:1 catheterizations to CABGS has occurred (133). In NL, the recent addition in 2002 of a second catheterization laboratory ensures that the referral rate for coronary angiography will continue to increase. Finally, the advent of angioplasty + stenting has increased the indications for PTCA, a change in practice which could alter the need for CABGS.

The benchmark for CABG surgery, as determined by the 1994/95 study, now appears inadequate, given that the assumptions on which it was based have changed dramatically.

Effective delivery of CABGS to the community implies that surgery be undertaken for appropriate patients, that reasonable waiting periods occur, and that those patients who need the procedure receive it (108). Therefore, a revisiting of current benchmarking data for CABGS is vital to ensure appropriate and reasonable allocation of resources.

1.2 Purpose of Study

The primary objective of the current investigation was to review the need for CABGS. Consensus guidelines were utilized to objectively ascertain the appropriateness, necessity, efficiency, and quality of care for CABGS in 1998/1999. The original benchmarks from 1994/95 were revisited and current and future need for CABGS in the province were predicted. By comparing both study periods, the findings have numerous implications for government policy and can be used as a guideline for resource management in the Cardiac Care Program.

1.3 Introduction to Coronary Artery Disease

As the second leading cause of death, cardiovascular disease accounts for approximately 27% of Canadian mortality (129) and ischemic heart disease (IHD) accounts for almost 90% of heart disease (120). The disease is a direct consequence of inadequate supply (perfusion) relative to the demand for oxygenated blood in the heart, resulting in a state of myocardial ischemia. Although initially reversible, longer periods of ischemia cause increased amounts of necrotic myocardium. When demand exceeds supply, it is also characterized by reduced availability of nutrient substrates and inadequate removal of metabolites (120). Atherosclerosis and thrombosis, causing narrowing and hardening of coronary arteries, are the most important pathogenic mechanisms leading to ischemia (120). For this reason, it is often termed coronary artery disease or coronary heart disease, and is considered to reflect critical stenosis of the major coronary arteries. In most cases, it results from decades of silent, slowly progressive coronary

atherosclerosis, manifesting in late adulthood (over 40 years of age) (42,75).

Major risk factors for CAD include increased age, smoking, diabetes, hypertension, dyslipidemia, and a positive family history. Females demonstrate a protective effect during reproductive years due to hormone production (120). Minor risk factors identified consist of obesity (> 30% above ideal weight), sedentary lifestyle, and major depression.

1.4 Treatment of CAD

Lifestyle changes are recommended, most specifically, dietary modifications to reduce fat intake and, in turn, atherosclerotic accumulation. Exercise can improve weight control, reduce hypertension and dyslipidemia, and help maintain glycemic control. Lipid modifying therapy and blood pressure control are considered vital preventative measures to minimize risk factors for CAD. Smoking cessation reduces risk of death by 50% (52).

Medical therapy is commonly used to alleviate symptoms and complications of CAD. Nitrates are used for symptomatic control of acute symptoms (27). Beta-blockers, considered a first line therapy, reduce mortality by reducing heart rate, contractility, and blood pressure, thereby maintaining low oxygen demands. In addition, maximal medical therapy usually includes calcium channel blockers, which reduce left ventricular afterload via arteriolar dilation. By blocking calcium channels, heart contractility is also reduced. Triple combination drug therapy enhances perfusion while decreasing demand, enabling adequate oxygen and nutrient delivery to this vital organ (27).

Finally, treatment of CAD can also include coronary revascularization. Revascularization may be undertaken by surgery or by balloon angioplasty. The need for these procedures is determined by coronary angiography (CA) (137). Albeit non-permanent solutions, revascularization is often offered to relieve symptoms and to prolong life. Percutaneous

transluminal coronary angioplasty (PTCA) with stenting, a stabilized balloon that inflates the narrowed artery so as to allow greater perfusion to the myocardial muscle, is widely used for single, double, and triple vessel artery disease. The addition of stenting has greatly expanded the indications for PTCA and likely, decreased the demand for CABGS.

1.5 Coronary Artery Bypass Grafting Surgery

Coronary artery bypass grafting surgery is now an established treatment for CAD. In 1669 Richard Lower demonstrated possible anastomosis between coronary arteries (122). However, it wasn't until 1968 that Bailey and Hirose performed the first experimental surgery in humans (10). Since that time, the techniques for CABGS have greatly improved (122). CABGS provides newly grafted vasculature to the heart so that old, atherosclerotic vessels are bypassed. It has been shown to prolong survival and improve the quality of life for many patients (117).

Like other surgeries, CABGS can have serious complications. Although advanced techniques and familiarity have reduced operative mortality and morbidity, the surgery is still reported to have a risk of death ranging from 1-5% (117). Other cardiac complications include arrhythmias (10-40% of patients) and myocardial infarctions (MI's) (6-8%) (117). Some, (10-20%) of patients experience complications that require extended hospital stay. Frequently, infections are the cause of prolonged length of stay. Stroke occurs more often in older patients (1-5%). Significant neurological abnormalities have been found in as many as 61% of patients (117). Furthermore, cognitive function is sometimes reduced following surgery and psychiatric complications have been reported (117). Numerous other complications have been detailed (fractures, pericardial effusions, anemia, etc), but risk for an individual patient is very low (117). Nevertheless, patients most often feel the surgery was beneficial, as it dramatically improved quality of life (105,117).

While CABGS is neither appropriate nor necessary in every patient with CAD, it is often utilized for symptom control. Ultimately, clinical decision-making and an educated judgment are required. While the evidence base is incomplete, CABG surgery has been shown to be superior to angioplasty and/or medical therapy for some patients. It has a survival benefit for patients suffering from stable angina with left main coronary disease, three-vessel disease with depressed left ventricular function, or multi-vessel disease with significant proximal left anterior descending (LAD) stenosis (24,75). It is also indicated for patients with unstable angina who continue to have pain despite aggressive medical therapy, who have an evolving MI, or who have complications of a failed PTCA.

Table 1.1 Indications for CABGS

Indications	Coronary artery stenosis
Stable Angina	Left main
	3-vessels ± reduced ejection fraction
	Multi-vessel with proximal LAD affected
Unstable angina	Evolving myocardial infarction
	Failed medical therapy
	Failed PTCA

CHAPTER II

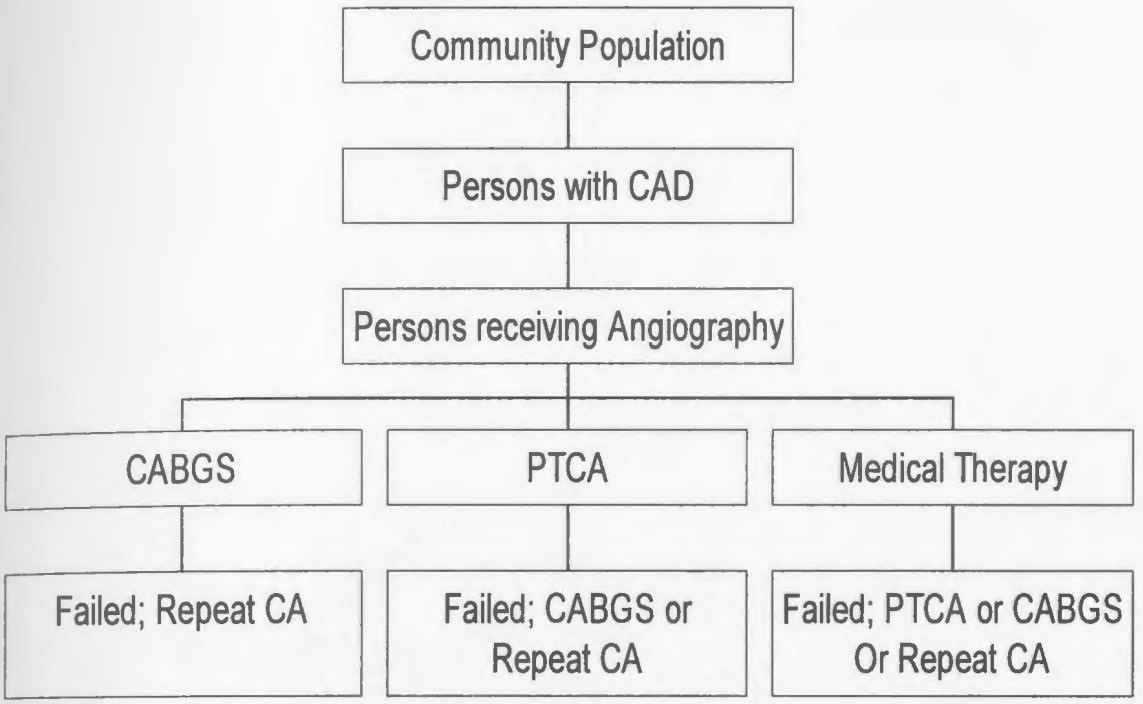
Review of the Literature

2.1 Introduction

Coronary artery bypass grafting surgery has been used in Canada for over 30 years; yet, extensive waiting lists have continued to mount since the early 1980's (104). Public polls show that nearly 2/3rds of Canadians believe that waiting lists, particularly for CABGS, have increased substantially in recent years (33). It may be hypothesized that in times of financial restraint, under utilization of a necessary intervention would be detrimental to the health of the community; conversely in times of easy access to a procedure, over utilization would occur with an associated loss of effective care being provided. Hence, there is considerable demand for this service to be used at an appropriate rate and therefore an enhanced interest in assuring effective delivery of the service for the payer, the provider, and the patients. It is thus necessary to determine optimum rates of utilization to ensure appropriate delivery of care.

Appropriate CABGS usage should ensure that only necessary surgeries are performed with good outcomes and within a reasonable period of time. Assessment of the optimal annual utilization rate depends on the ability to determine appropriate use in the population. It should be based on objective, reproducible guidelines using available client assessments and documentation. It is also dependent on setting reasonable criteria for the assumptions on which the rate is based. The rate of CABGS will be influenced by: 1) the rate of cardiac catheterization, 2) the rate of PTCA utilization, 3) development of new technologies, 4) demographic change in the population, and 5) indications for CABGS.

Figure 2.1 Flow Diagram To CABGS



2.2 Benchmarking the Need for CABG Surgery

In order to determine the appropriate allotment of resources, need may be defined as a population-based rate. Benchmarking data aim to provide a guideline, which allows the service provider a means to satisfy need and monitor productivity. Benchmarking the need for CABG surgery must consider the availability of coronary catheterization, which ultimately controls the flow to the operating room. However, simply supplying service at this rate is not assurance that all clients who need the service receive it. It is anticipated that criteria must also determine that the procedure is applied appropriately and prioritized effectively. Finally, the quality of service delivery should be high. Thus, an accurate benchmark requires that these conditions are met. Since the rate of cardiac catheterization is the limiting factor in identifying patients who need CABGS, it is hypothesized that access to coronary angiography will predict need. Whilst the

researchers have utilized this changing access to predict increasing demand, it is essential first to document the appropriateness and necessity of current utilization.

2.3 Assessment Tools for Measuring the Necessity of CA and CABGS

In an attempt to define the right rate, researchers have focused on identifying underuse and overuse of procedures. Almost all objective tools were designed with the intention of aiding physician/surgeon decision-making (87,138). Bernstein et al., compared 3 methods designed to aid in the decision making process (19). Two of these were consensus procedures while the third method used a decision algorithm model. They found that although the panels (Dutch and American) had high agreement, the algorithm model was not consistent with the panels and did not accurately reflect physician practice. In Newfoundland and Labrador, like other Canadian settings, the decision to refer patients for CABG surgery is one of consensus. The cardiovascular team, comprising of cardiologists, surgeons, and other relevant physicians, discuss the patient's indication and history and decide on the treatment plan. Because Canadian practice utilizes team management, it is not surprising that the more valid assessment tools use a consensus procedure (6,11,40,74,86,126,142).

The RAND Corporation, a nonprofit institution based in the United States, attempts to improve policy and decision-making through research and analysis. They have devised a methodology that has been applied in the benchmarking debate (20,64). Six frequently performed and resource intensive procedures, including CA and CABGS were examined. The researchers used a consensus process to synthesize expert opinion. The cardiovascular panel consisted of 1 family physician, 2 internists, 3 cardiologists, 2 cardiothoracic surgeons, and 1 radiologist. Project staff organized a comprehensive and thorough review of the literature and clinical definitions were established. Indications were then organized into chapters of clinical

similarity (stable angina, unstable angina, etc). Panel members were asked to rate each indication on appropriateness and necessity on a scale of 1 through 9 (1 being inappropriate or not necessary). Appropriateness of the procedure was defined to mean that the expected health benefit exceeded the expected negative consequences by a sufficiently wide margin so that the procedure was considered worth doing, exclusive of monetary costs. Necessity, in contrast, was applied only to those indications deemed appropriate and its definition was more stringent. A procedure was considered necessary only if the physician felt obliged to recommend it to the patient as being the best clinical option available. Mean ratings were then accrued and the panel convened for 2 days. Project staff led discussions and all indications were revised when required.

While numerous manipulations can be construed from the data, the panel's findings enable researchers to utilize various definitions according to their own local practice. The authors have deemed the procedure appropriate or necessary if the median rating was between 7-9 without disagreement between panel members, inappropriate or not necessary if the median was 1-3 without disagreement, and equivocal if there was disagreement or the median rating was 4-6. The RAND method has been used by other panels, who created their own ratings to apply to local practice (12,47,50,64,119). Appendix A provides a sample of necessity ratings for CABGS. The remainder of the literature review will address the use of these CABGS ratings.

2.4 Review of the RAND Technique

The RAND technique has been extensively used and validated (1,31,42,93,94,97,98, 100,102,103,125). Based on a comprehensive review of the literature, the procedure applies both accrued information and experience in its application. The ability to apply various definitions of agreement and disagreement provide flexibility for future researchers to use as needed.

Furthermore, clinical definitions can be altered to allow application to various settings (110). The authors have provided ratings in a relatively short time period and at a limited cost.

2.41 Limitations of the RAND Methodology

The use of an evidence based consensus procedure does have some serious concerns. First, the inherent usefulness is questioned (65). Next, the effect of the rater (expert-specific deviation) has limitations (114). Finally, there is a measurement error component (132). Current ratings, based on the 1991 ratings, may be outdated. There has been considerable advancement in technique and equipment since that time, as well as substantial changes in the surgical procedure. For instance, off-pump CABGS, which reduces the need for ventilatory assistance and decreases length of stay, mortality, as well as morbidity, has decreased the cost per procedure and has become almost routine (43,88,116). Indications for coronary angioplasty have greatly expanded and outcomes have continued to improve (23,37,118). A revised literature review and renewed application would yield more precise ratings. The RAND corporation did not clarify which risks or benefits it has considered in its deliberations (57). Further, it did not make the intended outcome of care explicit, a problem because different people may have different aims and expectations for care. Moreover, it has been criticized for ignoring patients' preferences and trivializing the visceral judgments doctors reach during consultation (57). Finally, although content validity is assured via consensus, sensitivity and specificity cannot be determined due to the lack of a gold standard. The inherent usefulness of the RAND technique to identify over and under use remains controversial (2).

2.42 Definitions

Under the RAND schemata, a procedure is deemed appropriate when the expected health benefits exceed the expected negative consequences. This rating tends to err on the side of

intervention as it is derived following assessment of net potential gain (64). Conversely, necessity was ascertained only when the physician felt obliged to recommend CABGS as the best clinical option available. Further, indications given a high necessity rating were generally those for which surgery was expected to improve life expectancy. However, from a meta-analysis of randomized trials comparing early surgery to initial medical therapy, researchers have derived a model showing that the magnitude of life expectancy gains from CABGS has a complex relationship to multiple factors, which were not considered by the expert panel (93,141).

In the application of the RAND method, clinical definitions were the same as those previously used by numerous researchers in addressing the question of varying rates (4,42,44,54,93,100,105). Of course, reliability was enhanced in this manner. Nevertheless, the technique has been criticized because these definitions considered neither resources (monetary costs and restraints) nor patient objectives or preferences (57). For the present study, these definitions were an accurate determination of need since the Canadian health care system does not assess the financial considerations of treatment. The application of medical procedures has always been highly debated and perfect agreement is rarely achieved.

2.43 Internal and External Validity

Based on clinical scenarios, the RAND indications have high content validity (20). Internal consistency was enhanced by discussion and feedback (111). Disagreement was found on approximately 17% of indications, which may have reflected accurate discrepancies in clinical practice or may have been indicative of bias in the methodology (111). However, it is likely that this instead reflects a lack of available concrete evidence, and hence, the lack of consensus regarding efficacy, highlighting areas wherein knowledge was inconclusive (111).

Fink et al. conducted a review of the literature to determine evidence available to the average physician (39). The findings supported levels of disagreement in the RAND method, signifying the need for more clinical evidence regarding some indications. Shekelle et al. documented the reproducibility of the method (125). Panelists were nominated by a variety of organizations and randomized to 1 of 3 panels. For CABGS there was moderate to high levels of agreement on appropriateness and necessity with approximately 95% agreement between panels (125). This suggests the technique is a valid and reliable tool for assessing under use of this procedure.

In response to criticisms regarding lack of external validity for necessity scores, Kravitz and colleagues assessed outcome measures for patients receiving recommended surgeries as compared to those for whom surgery was not suggested (70,71). Death and frequency of chest pain were examined. Adjusting for the degree of coronary artery stenosis (70% of proximal LAD), risk factors, and ejection fraction, patients who received surgery within 1 year had a 50% reduction in mortality and had a significant reduction in chest pain as compared to those who did not receive surgery (70).

2.44 Inter-Rater Variability

The rater effect varies depending upon regional affiliation as well as on person specialty. Ratings vary between nations even when presented with the same research evidence and when asked to ignore economic considerations (21). Nevertheless, Shekelle demonstrated that Canadian panels showed high levels of agreement on necessity ratings (95%). It was noted however, that disagreement was substantial for appropriateness ratings (125). Panel members displayed systematic and random variation in rating indications. Member specialty contributed to judgments of efficacy; for example, surgeons deemed the service more appropriate as compared to family physicians. But, the literature was less revealing about the size or the extent

of this difference (57). Furthermore, surgeons were also less likely to conform to the panel median as compared to primary care givers (80). Primary care physicians were most likely to conform following discussion, while cardiologists were most accurate when considering the median rating as gold standard. Yet, these differences affected less than 1/6 of clinical cases examined (63, 80). Discussions were led by a chairperson, which may have imposed value judgments and influenced panel discussions.

2.45 The Canadian Model

In 1994, in conjunction with the original investigators, Canadian researchers sought to replicate RAND findings using Canadian definitions and panel members. In "Coronary angiography and revascularization: defining procedural indications through formal group processes," Kahan et al. investigated interphysician agreement within and between 2 panels (64). The Canadian criteria used a stringent disagreement definition and defined disagreement to be when 3 or more ratings were in the lowest 3-point range and 3 or more ratings were in the highest 3-point range, a demanding definition using only 9 panel members. It was likely that this definition over-estimated the appropriateness of surgical procedures by assuming agreement when the panel was, instead, largely in contention. Clinical definitions were altered to suit Canadian practice. Again, investigators found that agreement was enhanced through the consensus procedure and was dependent upon the composition of the panel (80,101). However, there were no significant differences between either of the Canadian panels in terms of their agreement or disagreement.

2.46 Conclusion

Although criteria should now be updated to include relevant medical literature, the RAND method of rating appropriateness and necessity is cost effective and generalizable. It has

been successful in aiding physician judgment, identifying areas of concern, determining over utilization and benchmarking the need for CABGS. Although it was subjective, it combined the expertise of experienced physicians and the knowledge of existing clinical literature. This seems to be a reasonable design when considering the imprecise nature of medical science and the subjectivity of everyday clinical decision-making. Based on the deliberations of expert panels, the technique blends evidence with inference, melding facts and values without delineating the degree of net benefit for specific indications (92). The APPROACH study, recently published from Alberta and now initiated in BC and other provinces, also uses these techniques and hence, this may indeed be the best method for comparative data in the Canadian system at this time (37). In the current NL investigation, use of RAND criteria permitted comparison of clinical practice from 1994-1999. Expert opinion can provide valuable information when there is conflicting or incomplete knowledge in the literature regarding the efficacy of any medical procedure, as is the case for CABG surgery (2). While no global standard has yet been established, the RAND technique has persisted in dominating medical literature on appropriateness of coronary revascularization (57).

2.5 Application of the RAND Methodology

Researchers have utilized RAND criteria to assess appropriateness of utilization in an attempt to identify over use of CABG surgery (77,85,140). Rates of inappropriate use in Canada ranged from 1 through 4% using the Canadian criteria (18,42,78), while American studies have found rates of inappropriate use from 4 to 17% (17,28). Publications from the United Kingdom have reported rates of inappropriateness as high as 16% while Sweden have demonstrated rates as low as 2% (11,16). High inappropriate use implies excessive application of this procedure, without incurring much likely benefit. Mcglynn and colleagues found evidence to suggest that

international variations in definitions and practice standards strongly influenced these rates and care should be taken to ensure appropriate guidelines are applied (85).

In efforts to determine under utilization, the scenario becomes much more complex. It requires assessment of all patients with critical coronary artery disease. This assumes that all symptomatic patients deemed likely to benefit from CABGS receive a catheterization, a difficult assumption to test. In effect, the cardiac catheterization laboratory is the site that controls the flow to the CABGS operating room (137). Approximately 30% of catheterized individuals will require CABGS (133). Thus, under use of this laboratory is indicative of a shortfall in identifying patients. Asymptomatic patients do not present to the health care system, resulting in the failure to identify persons for whom surgery might be deemed necessary. Additionally, all surgeries completed should be necessary and patients should receive the service efficiently. A breakdown in either of these components would likely indicate ineffective use of this procedure.

Although much less has been published regarding the application of necessity measures for CABGS, some studies have looked at necessity in determining disparity in access. Gender, race, age, income, geographical location, and size of Cardiac centre have all been examined to determine biases in the referral of necessary surgeries (3,28,40,47,50,70,74,76). Fox et al., again using Canadian criteria, assessed all patients diagnosed from the cardiac catheterization lab with critical coronary artery disease and demonstrated high necessity scores for CABGS in Newfoundland and Labrador (94%); suggesting that the vast majority of surgeries completed were required (42). However, they also identified an additional 31 patients with critical CAD (9%) for whom surgery was recommended according to the necessity scores but who were not referred for CABGS. Moreover, they demonstrated that the difference between the number referred for CABG surgery and the number performed was substantial. Kravitz et al. concluded

that patients who received necessary surgery within a 1-yr period had lower mortality as compared to those who did not (8.7 vs. 15.8%, p=0.01), indicating that necessity score has external validity in determining under use as demonstrated by a survival advantage (71).

2.6 Utilization Rates of CABGS

In addressing current capacity, researchers have noted considerable variation in rates of utilization. In 1986, Wennberg commented on the ubiquity of variations in population-based rates of surgery (138). CABG surgery proves to be no exception. There is an abundance of literature targeted towards identifying these geographical variations and determining which rate is right (3,4,28,105,121,133). Previous research has found considerably higher rates of utilization in the United States as compared to Canada (3,48). However, Canadian rates of cardiovascular procedures are in the moderate to high range when compared with nations other than United States (16,38,81). Complicating the matter, there continues to be local discrepancy in rates (58,90). In a national comparison of cardiovascular rates in 1991, the Canadian average was 50 CABGS / 100,000 population. While provincial rates ranged from 25 through 78/ 100,000, NL was performing 47/100,000 population CABG surgeries at that time (59).

Whilst this has been the focus of research for numerous years, it has been presumed that these variations reflect local practice variations and differences in the application of methodology. Furthermore, health care policies influence access and thus, population rate. While there are no clear explanations, it emphasizes the importance of defining local need and using consistent methodology.

2.7 Consensus Based Priority Scores

Prioritizing patients for care in a queue-based system is a complex task. Priority scores for CABGS have also been established using an evidence-based consensus method. However, as

mere strategies for action, they do not consider patient request or circumstances such as geographical or financial restraints. Furthermore, the literature on this topic remains uncertain as to the precise benefits of faster wait-times to CABG surgery, and variations are easily detected in the scoring system. Priority scores for CABGS depend on the presence of angina symptoms. This likely results in an underestimate of priority for patients, as some patients who require CABGS are asymptomatic or have chronic heart failure.

Naylor has utilized regression to identify the variables that most consistently reflect priority scores and has devised a simple and short method by which to estimate a patient's appropriate wait time (95). The variables included are based on coronary anatomy, clinical presentation, response to medical therapy, and the results of non-invasive tests of ischemic risk (95). Ranks ranging from 1 -7 can be computed for each patient and are associated with a maximum recommended wait time. Recommended wait times progressed through emergency revascularization (immediate), very urgent (< 24 hours), urgent (<72 hours), semi-urgent (prior to discharge, within 2 weeks of referral), short elective (6 weeks), delayed elective (3 months), and finally, marked delay (6 months). Initially, there was panel agreement for only 60% of cases. Another study found that for 48/49 scenarios, 75% of urgency ratings fell within 2 contiguous points on the scale (98). However, Naylor and colleagues found that physicians did benefit from feedback and the use of consensus criteria as aids in their decision-making, as indicated by improved agreement (96). Despite its limitations as a consensus procedure, it was based on a thorough review of the literature and was representative of Canadian practice and beliefs. It too, has been extensively used and validated (1,31,42,93,94,97,98,100,102,103,104, 125).

In an effort to appraise the efficacy in NL, Fox et al. retrospectively applied these criteria to all patients referred for CABGS (42). They demonstrated that only 46% of patients received surgery within the recommended waiting time, with more urgent patients most likely to exceed the wait. In comparison, Naylor and investigators revealed that almost 80% of patients in Ontario underwent surgery within the proposed wait time (99,102,103). Again, very urgent patients were less likely to receive their surgery on time. Such evidence suggests lack of access to CABG surgery in Newfoundland and Labrador.

2.8 Managed Delay

Under utilization can also be detected by the existence of extensive waiting periods. Waiting lists, although not an ideal solution, have become a practical and defendable solution if considered a temporary delay in the delivery of a service and if there is no significant adverse impact on patient health (30). Indeed, a policy of managed delay has advantages over systems based on financial consideration since access to health care can be determined according to urgency of clinical need (94). Furthermore, it necessarily limits supply, encouraging optimum use and reducing rates of inappropriate use. Waiting lists are considered ethical only if they are based on medical need, are associated with low risk, and if they are measured, monitored and managed in an effective manner so as to provide service within an appropriate period of time (91,96). Canada's primary goal in health care management is to facilitate reasonable access to health services without patients encountering barriers (30). Accordingly, it is of considerable importance to optimize queue-based allocation of scarce resources and to ensure safe and fair application of these queues (99).

If not managed properly, prolonged waits for a needed surgery place considerable emotional and financial burdens on the patient, the service provider, and the payer. While one of

the objectives of CABG surgery is to improve the quality of life by reducing symptoms and/or limitations that result from having CAD, many patients experience heightened anxiety throughout the waiting period (127). Extended waiting periods and repeat cancellations contribute to a state of uncertainty and fear. In fact, these feelings can be more disturbing than the chest pain itself (13). Patients have expressed dissatisfaction with their lives and health status, reporting high frequencies of symptoms of fatigue, shortness of breath, chest pain, depression, stress, substance abuse, and sleep disturbances (12,61,134). Likewise, relatives of patients have indicated higher levels of anxiety, depression and irritability as compared to control groups (15). In addition to this, it has been found that patients have an increased risk of psychological disturbances for 2 years following surgery (61). From a biomedical perspective, there is risk of an adverse event while awaiting surgery. Canadian estimates suggest that the risk of death ranges between 0.4 and 1% while the risk of a non-fatal myocardial infarction (MI) or a change in clinical status requiring urgent admission is between 0.1 and 12% (14,26,31,89,102,103). However, other studies have found the risk of death to be over 2% and the risk of a non-fatal MI or worsening clinical status to be almost 20% (14,34,61). These patients are often unable to work and their daily activities are severely minimized. Thus, the financial burden on families can be taxing (12). Delay in surgery is a very difficult situation for the physician as well. Physicians face conflicting responsibilities to both the individual patient and to society. They cannot simultaneously be advocates for their patients and also serve as financial guardians of the health care system without incurring divided loyalties and ethical peril (82,131). The difficulty with delaying beneficial surgery expands beyond emotional and ethical dilemmas; there may also be legal implications for doctors and health care management (91). Moreover, changes in clinical status require readmission, and reinvestigation is often necessary

following prolonged waits. Cox and colleagues found that almost 9% of patients required readmission during the waiting period (31). This constitutes considerable additional costs to the health care provider and often compromises the health of the patient. Previous investigations have also reported that delayed surgeries contribute to prolonged hospital stay, higher drug use and more post surgical rehospitalization (26,35). It may decrease the possibility of returning to work following surgery, furthering the impact on society (35,130). Thus, there is economic incentive to minimize the risks and burdens associated with these waits. Education and good patient-doctor relations may reduce anxiety and contribute to a better experience for the patients, families, and medical team. It is of fundamental importance to apply and effectively manage patient queues so that access is judged safe, fair, and justifiable, not simply economically but medically and ethically as well (30).

Nonetheless, managed delay helps to control service usage and guarantees at least moderate efficiency because it necessarily limits access. Delay may still be beneficial for some elective cases. It offers the patient time for sober thoughts and time to prepare for surgery while allowing urgent cases immediate attention (91). However, the average Canadian waits 149 days for surgery (90). Although this occupies middle ground in international comparisons, some have suggested that wait time should not exceed 42 days (68).

2.9 Predicting Future Need

In addition to concerns addressing the need for CABGS, there are considerable difficulties in extrapolating this data to future years. While the assumptions used to benchmark this need must be continuous, the trends must also be stable. In times of fiscal restraint, this consistency is almost never attained. Exacerbating this effect, a growth in the proportion of elderly people in the population is expected to greatly escalate the need for coronary

revascularization by increasing the population at risk (41). Improvement in techniques, technology, and physician familiarity permit high-risk patients to be treated and encourages late stage treatment, thereby expanding existing indications for this procedure (36). In contrast, patient awareness of risk factors for CAD has risen dramatically. It can be inferred that this may reduce the incidence of the disease in coming years (60). Yet, it has been found that lifestyle adaptation has minimal influence in the development and progression of heart disease (107). Conversely, the advancement of medical therapy and PTCA may diminish the need for CABG surgery (37,41,60,93,115,118). Even so, medications for reducing blood pressure or cholesterol are not optimally used (9,139). Furthermore, Serruys and colleagues have found that CABGS continues to be the gold standard for treatment and has better outcome statistics for many indications as compared to PTCA (23,115,117,124). Increased access to cardiac catheterization will undoubtedly lead to more comprehensive and earlier identification of patients with critical coronary artery disease and consequently, an increase in the possible candidates who may benefit from CABG surgery (137). As a result of these varying factors, it would appear necessary to continually review the utilization of CABG surgery, taking account of growth in angiography access and changing assumptions and thus enabling appropriate benchmarking figures.

2.10 Summary

It is acknowledged that, 1) benchmarking the need for CABGS is useful in the effort to contain and appropriately distribute health care resources, 2) the consensus procedure can aid in the physician decision-making processes, and 3) an objective and reliable tool designed to measure appropriateness, necessity, and priority can provide informative feedback and monitoring if applied suitably. The RAND method has proved to be a valid means by which to achieve this task.

CHAPTER III

Design and Methods

3.1 Introduction

A retrospective cohort study was performed in a tertiary care hospital in Newfoundland and Labrador in 1994/95 in efforts to appraise the need for CABGS. The findings indicated that CABGS was being appropriately and necessarily applied; but the access to this service was far less than ideal. Following the infusion of $1.5 million and restructuring of the health care system after 1995, it is vital to review the assessment of need. This chapter contains the method by which we achieved this assessment.

3.2 Research Design

The Health Sciences Cardiac Program is the sole source for revascularization services in Newfoundland and Labrador, responsible for a population of 402,000 persons over the age of 20 in 1999. All consecutive patients who underwent coronary catheterization during 1 year (1998-1999) were prospectively studied, in addition to the cohort of patients who received CABGS during the same study year. The waiting list was evaluated prior to the study's inception as well as following completion of the study. We evaluated: the current need for CABGS in NL, the appropriateness of utilization, the necessity of utilization, the waiting times for CABGS, the quality of care delivered with this service, and the future need for CABGS in NL.

3.3 Ethics

The study was granted approval by the Human Investigation Committee at Memorial University of Newfoundland and Labrador. Information was obtained and recorded from patient charts. A study number code on each abstraction form was used to maintain confidentiality and only the primary investigators had access to the list of subjects and respective codes. The

physician name was not recorded and neither patient nor physician was identified by name in any report or publication. Accrued data from the Cardiac Program of the Health Care Corporation of St. John's was reviewed to determine utilization rates of procedures from 1994-2002.

3.4 Sample Selection

All patients receiving angiography were assessed for appropriateness using patient demographics, indications, and resultant angiographic data. All patients with critical coronary artery disease (defined as a stenotic lesion > 50% in either the left, right, or circumflex artery) at time of coronary angiography were identified and followed through cardiovascular rounds where decisions concerning revascularization were made. Two groups of patients were identified and studied; the first consisted of all those who received a referral for CABG surgery during the study period (August 18, 1998 through August 13, 1999) while the second consisted of those clients who received surgery throughout the same period. Two patients were ultimately excluded due to missing data. In those patients referred for surgery, we evaluated several key components in service delivery. By applying the RAND criteria, we assessed the appropriateness and necessity of CABGS utilization. Further, we determined the efficiency of service as indicated by the management of the queue-based service. This was accomplished using Naylor's priority scoring and following the referred cohort.

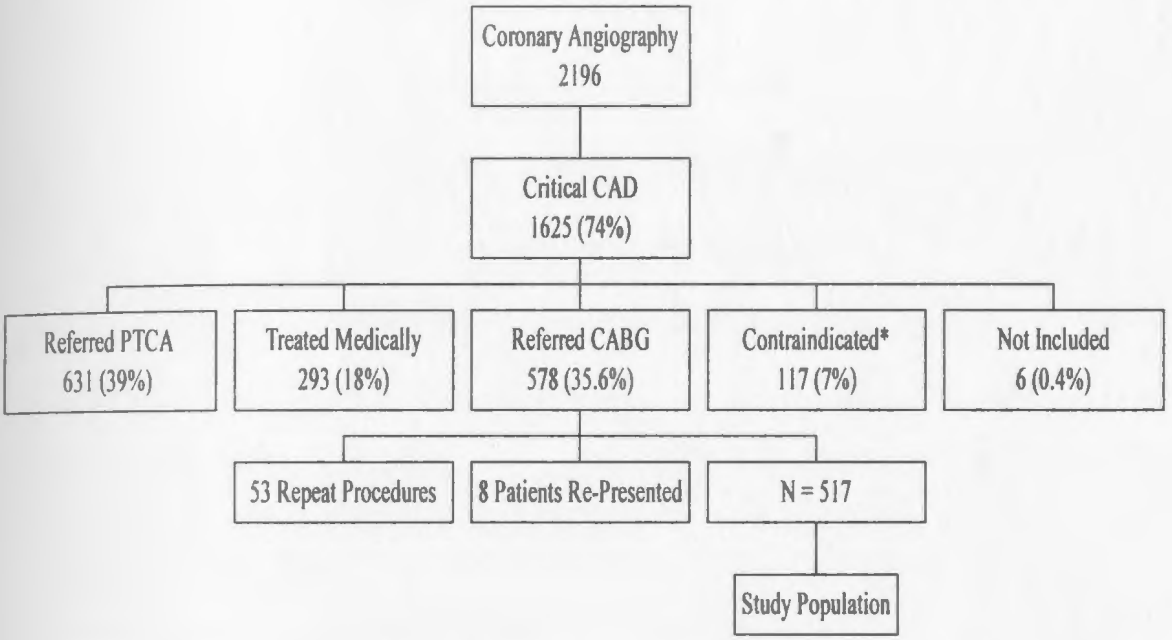
Finally, we determined the current need for CABGS in Newfoundland and Labrador and made predictions for future need based on the compilation of bypass and angiography utilization data and demographic population trends.

3.5 Study Population

The cardiac booking registry reported 2196 procedures in the study year, 1625 patients were identified to have critical coronary artery disease. Although 578 referrals for CABG

surgery were made, many of these were repeat procedures. Only 517 patients were actually referred for de novo surgery during the study period and 434 surgeries were performed.

Figure 3.1 Study Population



*Contraindicated: Terminal illness, such as cancer, AIDS, severe COPD (chronic obstructive pulmonary disease), hepatic failure, where a reasonable prognosis is 6 months or less, advanced dementia, or severe impairment in ability to perform the basic activities of daily living because of noncardiac disease. Many of these patients ultimately received medical therapy.

3.6 Research Instruments

3.61 Data Collection Instrument

A standardized data collection instrument (Appendix B) was developed for this study. It consisted of 3 parts. The first section included demographic information, such as age, sex, cardiac risk factors, clinical presentation, angina symptoms, date of coronary angiogram, relevant medical history, cardiac medications and response to medical therapy, left ventricular ejection fraction, the results of non-invasive and invasive tests of ischemia, and coronary artery anatomy. This information was collected on all patients receiving coronary catheterization during the study period. Part II was completed on all patients with critical coronary artery disease and included information presented to the weekly cardiovascular (CV) conference team, including risk stratification information and CV round treatment decisions for patients (i.e. CABG surgery, PTCA, or medical therapy). Part III contained information on the quality of care for those who received revascularization during the study, including post-operative complications up until the time of discharge and surgery waiting times. When possible, photocopies of the cardiac catheterization, cardiovascular conference, and operative notes for each client were obtained and attached to the data abstraction form. In addition, discharge summaries, letters of consultation, and other relevant information were attached when the researcher felt it was necessary. The information from the 3 forms was used to determine appropriateness, necessity, and priority for CABG surgery. Definitions employed are presented in Appendix C.

3.62 Appropriateness, Necessity, and Priority Scores

The appropriateness and necessity scores, using RAND Corporation criteria, were derived for all charts and applied for both angiography and CABGS (Appendix A). Level of

operative risk was determined using Parsonnet risk stratification score (Appendix D; 112). This takes into consideration significant medical history, left ventricular ejection fraction, age and sex. Albeit a brief scoring of risk, it has proven to be a reasonable and cost-effective measure of co-morbidity. RAND ratings are dependent upon this categorization (112, 117). Using the scoring system of Naylor et al. (Appendix E), a priority score for queue time for surgery was also derived for each patient referred for CABG surgery (94).

3.7 Procedure

Data was collected by a research nurse with extensive experience in cardiology (GK) and by a Master of Science Candidate (the author) trained for this purpose. Patient charts were utilized. Patients receiving a referral for surgery were followed forward in time until a censor point had been reached. Patients were censored when: a) the patient received surgery, b) the patient was removed from the waiting list, or c) the last follow-up, being 6 months following the end of study date. Critical events (death, MI, change in status) were noted. Patients receiving surgery during the study period were followed until time of discharge noting various complications and mortality. All definitions were clearly defined and were the same as those used by Naylor and colleagues. Abstraction forms were reviewed to ensure consistency and completeness and a comprehensive check was made to determine accuracy. In addition, random checks were made to ensure correctness.

Two trained personnel (GK and the author) independently computed appropriateness and necessity of angiography and CABGS for all subjects identified with critical coronary artery disease and for those who received CABG surgery during the study period. Inter-rater reliability was monitored using the Kappa statistic to ensure high consistency (kappa = 0.92). Scores were compared and discrepancies settled by arbitration in consultation with the chief investigator (PP;

physician). Appropriateness scores evaluated decision-making by the CV conference team and were applied to all patients referred for CABGS. Using RAND suggestions, necessity of CABG surgery ≥ 7 was considered a recommendation for treatment and these recommendations were compared to cardiovascular reports and attendance records to determine agreement in treatment decision-making. Priority scores were determined for all patients referred for CABG surgery during the study period. These scores, associated with recommended waiting times, were compared to actual time to surgery.

3.8 Data Analysis

Data was entered in a Paradox database and analyzed using Statistical Package for Social Sciences (SPSS) software. Descriptive statistics were used to describe the samples and comparisons between groups were done using a Student's t-test, Pearson chi square statistic, and Fisher exact as appropriate. Kaplan Meier distributions of the time to surgery for varying priorities of urgency were constructed. Finally, these data were evaluated and used to document changes from 1995-1999. Utilization data from 1994 through 2002 were used to compare benchmarking predictions with actual need for CABGS.

CHAPTER IV

Results

4.1 Introduction

Using similar methods as those in the 1999 investigation, Fox et al., (Appendix F) retrospectively reviewed hospital records and also identified 2 groups of patients; those diagnosed with critical CAD and referred to CABGS between April 1, 1994 and March 31, 1995, as well as those patients who received CABGS during that period. This chapter will highlight the findings of both studies (hereafter referred to as 1995 and 1999 respectively) and note changes between time periods. The comparison findings have been published in The Canadian Journal of Cardiology (2004) and can be found in Appendix G.

4.2 Coronary Angiography

Despite increased utilization of CA's between time periods, patients waited an average of 5 days for cardiac angiography and 90% possessed at least 1 risk factor. A high level of appropriate usage was observed. Of 2071 CA's assessed for appropriateness using the RAND criteria in 1999, 74% (N=1534) were appropriate, 22% (N=457) were uncertain, and 4% (N=80) were inappropriate. In the inappropriate group, the majority (60%) were for chest pain of uncertain etiology. Cases in the uncertain group, compared with the appropriate group, were more likely to be over 75 years of age, less likely to have unstable angina, more likely to have other reasons (particularly heart failure) as the indication, and less likely to have a very positive exercise stress test (Table 4.1).

The proportion of patients diagnosed with critical CAD was slightly higher in the 1999 cohort compared to the 1995 cohort (from 68% to 74%). Although age and gender remained consistent throughout the 2 study periods, the later cohort was characterized by a significantly

higher proportion of class III angina (33 vs 14%), a lower proportion of very positive exercise stress tests (21 vs 40%), and less patients with ejection fraction less than 0.35 (14 vs 25%). By 1999, the threshold for CA had been lowered to include more patients with Class I-III angina (Table 4.2). Since 1995, the number of diagnostic coronary angiographies (CA) increased by 37% (from 1604 to 2196). The waiting list for CA's was 134 at the end of September, 1999. Angiography utilization increased by only 2.8% in the coming year while the waitlist increased to 343 by 2001. This implies that the catheterization laboratory was working at full capacity in 1999. A second catheterization laboratory was opened in 2002 due to the expanding waitlist.

4.3 Management of Critical Coronary Artery Disease

Table 4.3 shows a summary of treatment decisions in 1995 and 1999. The proportion of patients with critical CAD who were referred for CABGS remained relatively stable (36%), despite absolute CABG surgery referrals increasing from 391 to 578 (48%). While PTCA referrals increased by 137% (266 to 631 referrals), its proportion of those with critical coronary artery disease increased from 26 to 39%. Yet, medical therapy as a means of treatment decreased in absolute referrals from 358 patients to 293 (-18%). Tables 4.4 and 4.5 demonstrate the clinical characteristics of patients by treatment category.

Table 4.1 **Characteristics of Patients who Underwent Diagnostic Coronary Angiography (CA), Characterized by Appropriateness; 1999**

Characteristic	Appropriate (n=1534) N (%)	Uncertain (n=457) N (%)	Inappropriate (n=80) N (%)
Age > 75	57 (4)	126 (28)	2 (3)
Max medical therapy	1236 (80)	198 (43)	34 (43)
Exercise Stress Test			
Very Positive	335 (22)	31 (7)	0 (0)
Positive	550 (36)	194 (42)	8 (11)
Indication for CA			
Chronic stable angina	472 (31)	174 (38)	27 (34)
Unstable angina	642 (42)	117 (26)	2 (3)
Acute MI/Post MI angina	321 (21)	49 (11)	2 (3)
Chest pain (uncertain origin)	24 (2)	24 (5)	48 (60)
Silent ischemia	25 (2)	4 (1)	0 (0)
Other	50 (3)	89 (19)	1 (1)
Ejection fraction			
> 35%	1216 (88)	331 (79)	70 (95)
15-35%	143 (10)	63 (14)	3 (4)
< 35%	23 (2)	23 (6)	1 (1)
Coronary Anatomy			
Protected left main	7 (1)	6 (1)	0 (0)
Unprotected left main	83 (5)	18 (4)	0 (0)
3-vessel disease	417 (27)	108 (24)	6 (8)
2-vessel disease + PLAD*	125 (8)	34 (7)	2 (3)
2 vessels	194 (13)	60 (13)	3 (4)
1 vessel with PLAD	129 (8)	20 (4)	1 (1)
1 vessel	269 (18)	63 (14)	8 (10)
No critical CAD	309 (20)	147 (32)	60 (75)

* Proximal left anterior descending

Table 4.2 **Comparison of Clinical Characteristics of Patients Diagnosed with Critical Coronary Artery Disease (CAD)**

Characteristic	1995 (N= 1073) N (%)	1999 (N=1625) N (%)	P
Age, years (mean, SD)	60 (±11)	61 (±11)	NS
Male	760 (71)	1152 (71)	NS
Angina Class			
No angina/Uncertain	69 (6.4)	117 (7)	NS
Class I-II	108 (11.9)	131 (8)	NS
Class III	146 (13.5)	534 (33)	< 0.0001
Class IV	750 (69.3)	843 (52)	< 0.0001
Very positive stress test	436 (40)	326 (20)	< 0.0001
Ejection fraction <35%	268 (25)	226 (14)	< 0.0001
Coronary anatomy			
Left main	72 (7)	119 (7)	NS
3 vessels	328 (30)	568 (35)	NS
2 vessels	314 (29)	438 (27)	NS
1 vessel	359 (33)	500 (31)	NS

Table 4.3 **Changes in the Study Populations**

Variable	*1995 Investigation*	*1999 Investigation*	*% Change in N*
Total N	1857	2454	32.1%
Repeat Procedures	253	322	27.3%
Coronary Angiography	1604	2196	37%
Critical Coronary Artery Disease	1082 (68%)	1625 (74%)	50.2%
Referred CABG	391 (36%)	578 (36%)	47.8%
Referred PTCA	266 (26%)	631 (39%)	137.2%
Treated Medically	358 (33%)	293 (18%)	-18.2%
Contraindicated	58 (5%)	117 (7%)	101.7%
Not Included	10 (3%)	6 (0.4%)	- 40.0%

Table 4.4 **Demographic and Cardiac Characteristics of Persons with Critical Coronary Artery Disease by Treatment Decision; 1995***

Variable	*Medical therapy*	*PTCA*	*Contraindicated*	*CABGS*
N	358 (33.1%)	266 (24.6%)	58 (5.4%)	391 (36.0%)
Mean Age, yr (SD)	57.6 ± 11.2	59 ± 10.1	65.6 ± 9.8	61.9 ± 10.2
Male	252 (70.4%)	186 (70%)	43 (74.1%)	279 (71.4%)
Angina Class				
No angina/uncertain	54 (15.1%)	3 (1.0%)	3 (5.2%)	9 (2.3%)
Class I	54 (15.1%)	3 (1.0%)	0	2 (0.5%)
Class II	35 (9.8%)	4 (1.1%)	2 (3.4%)	8 (2.0%)
Class III	42 (11.7%)	28 (10.7%)	5 (8.6%)	71 (18.2%)
Class IVA	136 (37.9%)	61 (22.8%)	18 (31.0%)	77 (19.7%)
Class IVB	26 (7.3%)	28 (10.7%)	17 (29.3%)	81 (20.7%)
Class IVC	11 (3.1%)	139 (52.6%)	13 (22.4%)	143 (36.6%)
Coronary Anatomy				
Protected Left Main	2 (0.6%)	2 (0.7%)	1 (1.7%)	1 (0.2%)
Unprotected Left	1 (0.3%)		5 (8.6%)	60 (15.4%)
3-Vessel Disease	48 (13.4%)	30 (11.1%)	28 (48.3%)	222 (56.8%)
2-Vessel + PLAD	46 (12.8%)	50 (19%)	8 (13.8%)	52 (13.3%)
2-Vessel - PLAD	67 (18.7%)	47 (18%)	9 (15.5%)	35 (9%)
1-Vessel + PLAD	46 (12.8%)	53 (19.7%)	3 (5.2%)	15 (3.8%)
1-Vessel - PLAD	148 (41.4%)	84 (31.5%)	4 (6.9%)	6 (1.5%)
Ejection Fraction		NA		
No Data	2 (0.6%)		0	4 (1.0%)
> 35%	285 (79.6%)		29 (50.0%)	287 (73.4%)
15-35%	63 (17.6%)		21 (36.2%)	80 (20.5%)
< 15%	8 (2.2%)		8 (13.8%)	20 (5.1%)
Exercise Stress Test		NA		
Very Positive	113 (31.6%)		17 (36.2%)	198 (50.6%)
Positive	105 (29.3%)		10 (17.2%)	34 (8.7%)
Indeterminate	NA		NA	NA
Negative	NA		NA	NA
Not done/No data	105 (29.3%)		31 (53.4%)	159 (40.7%)
Max Medical Therapy				
Yes	NA	229 (86%)	NA	289 (85.5%)

* 1082 patients; 9 missing data

Table 4.5 **Demographic and Cardiac Characteristics of Persons with Critical Coronary Artery Disease by Treatment Decision; 1999***

Variable	*Medical therapy*	*PTCA*	*Contraindicated*	*CABGS*
N (%)	293 (18%)	631 (39%)	117 (7%)	578 (36%)
Mean Age, yr	60 (sd=11)	59 (sd=11)	64 (sd=12)	62 (sd=9)
Male	69.3%	66.9%	66.7%	77.0%
Angina Class				
No angina/uncertain	43 (14.8%)	22 (3.5%)	14 (12.0%)	37 (6.4%)
Class I	1 (0.3%)	0	1 (0.9%)	1 (0.2%)
Class II	45 (15.5%)	48 (7.6%)	6 (5.1%)	29 (5.0%)
Class III	87 (29.9%)	157 (24.9%)	39 (33.3%)	248 (42.9%)
Class IVA	24 (8.2%)	23 (3.6%)	5 (4.3%)	24 (4.2%)
Class IVB	40 (13.7%)	120 (19.1%)	18 (15.4%)	101 (17.5%)
Class IVC	51 (17.5%)	261 (41.4%)	34 (29.1%)	138 (23.9%)
Coronary Anatomy				
Protected Left Main	4 (1.4%)	7 (1.1%)	2 (1.7%)	0
Unprotected Left	1 (0.3%)	1 (0.2%)	6 (5.1%)	97 (16.8%)
3-Vessel Disease	48 (16.4%)	94 (14.9%)	75 (64.1%)	348 (60.2%)
2-Vessel + PLAD	22 (7.5%)	68 (10.8%)	9 (7.7%)	71 (12.3%)
2-Vessel - PLAD	64 (21.8%)	149 (23.6%)	15 (12.8%)	39 (6.7%)
1-Vessel + PLAD	23 (7.8%)	118 (18.7%)	2 (1.7%)	11 (1.9%)
1-Vessel - PLAD	131 (44.7%)	194 (30.7%)	8 (6.8%)	12 (2.1%)
Ejection Fraction				
No Data	15 (5.2%)	92 (15.0%)	5 (4.3%)	13 (2.3%)
> 35%	221 (76.7%)	481 (78.6%)	67 (57.8%)	473 (82.1%)
15-35%	46 (16.0%)	36 (5.9%)	31 (26.7%)	78 (13.5%)
< 15%	6 (2.1%)	3 (0.5%)	13 (11.2%)	12 (2.1%)
Exercise Stress Test				
Very Positive	36 (12.3%)	112 (17.7%)	21 (17.9%)	154 (26.6%)
Positive	113 (38.6%)	233 (36.9%)	33 (28.2%)	219 (37.9%)
Indeterminate	10 (3.4%)	8 (1.3%)	0	8 (1.4%)
Negative	18 (6.1%)	25 (4.0%)	2 (1.7%)	15 (2.6%)
Not done/No data	116 (39.6%)	253 (40.1%)	61 (52.1%)	182 (31.5%)
Max Medical Therapy				
Yes	194 (66.2%)	494 (78.3%)	94 (80.3%)	439 (76.0%)

* 1625 patients; 2 missing data, 4 received another therapy

In 1999, unstable angina was the most common indication for surgery (56%), stable angina followed with 24%. Sixty (60)% had triple vessel disease and over 82% had ejection fractions greater than 35. Most were on maximum medical therapy (76%) at the time of surgery. The operative risk was relatively low with 66% of patients at low risk while only 4.1% were deemed to be high risk. This represents a shift towards patients who were less acutely ill compared to 1995 data. The proportion of patients in the 1999 cohort with class III angina was higher (43% vs 18%), the proportion on maximal medical therapy was lower (76% vs 86%), and the proportion considered elective (prioritized between 6 weeks and 6 months wait-time), was higher (41% vs. 14%). The increase in the number of patients referred for CABGS could be solely attributed to the increase in the number of patients recommended for elective surgery. (Table 4.6).

This shift towards the less ill was facilitated by the growth in PTCA (refer to Table 4.1). In 1999, PTCA was predominantly used to treat the more acutely ill; 64% of those referred for PTCA had unstable angina and 78% were on maximum medical therapy. Twenty-six (26)% of patients had severe coronary artery disease; left main, triple vessel, or two vessel with proximal left anterior descending (LAD) disease. The comparable figures in 1995 were as follows: 86% who had a PTCA procedure had unstable angina, 86% were on maximum medical therapy, and 31% had severe coronary artery disease (Table 4.4 and Table 4.5).

Table 4.6 Changes in the CABGS Referral Cohort

Variable	1995	1999	Probability
N	391	517	
Mean Age, yr	61.9 ± 10.2	62.2 ± 9.4	NS
Male	70.4%	77%	0.05
Angina Class			
No angina, Class I or II	19 (4.9%)	57 (11.0%)	0.05
Class III	71 (18.2%)	205 (39.7%)	<0.0001
Class IVA	77 (19.7%)	24 (4.6%)	<0.0001
Class IVB/C	224 (57.3%)	215 (41.6%)	<0.0001
Coronary Anatomy			
Protected Left Main	1 (0.2%)	NA	NS
Unprotected Left	60 (15.4%)	87 (16.8%)	NS
3-Vessel Disease	222 (56.8%)	307 (59.4%)	NS
2-Vessel + PLAD	52 (13.3%)	62 (12.0%)	NS
2-Vessel - PLAD	35 (9.0%)	37 (7.2%)	NS
1-Vessel + PLAD	15 (3.8%)	13 (2.5%)	NS
1-Vessel - PLAD	6 (1.5%)	11 (2.1%)	
Indication for Surgery			
Stable Angina	49 (12.5%)	123 (23.8%)	<0.0001
Unstable Angina	275 (70.4%)	288 (55.8%)	NS
Acute MI	4 (1.0%)	2 (0.4%)	NS
Post MI	43 (11.0%)	82 (15.9%)	NS
Other	20 (5.1%)	22 (4.3%)	NS
Ejection Fraction			
No Data	4 (1.0%)	NA	NA
> 35%	287 (73.4%)	434 (84%)	<0.0001
15-35%	80 (20.5%)	67 (13%)	<0.0001
< 15%	20 (5.1%)	16 (3%)	NS
Operative Risk			
Low Risk	250 (64.0%)	341 (66.0%)	NS
Moderate Risk	101 (25.8%)	140 (27.1%)	NS
High Risk	40 (10.2%)	21 (4.1%)	NS
Max Medical Therapy Yes	289 (85.6%)	383 (74.7%)	<0.0001
Delayed Elective Priority	53 (13.6%)	201 (38.9%)	<0.0001

4.4 Referred for CABGS Cohort

In 1995, 391 of 1073 patients with critical CAD were recommended for CABG surgery (36%). By 1999, of 1625 patients, 578 were referred for CABGS (35%). However, repeat patients accounted for 61 of these patients; 53 patients received repeat angiography because they had waited over 6 months, and another 8 patients were presented again to cardiovascular rounds due to changing indications. Despite an increase in surgical procedures from 338 to 434 (28%), the cardiac unit was not able to meet the increase in demand. Over the same period of time, the waitlist had increased from 190 to 267 (49%).

In 1995, almost 99% of referrals for CABGS were considered appropriate with 1.2% judged uncertain. Necessity scores were also high, as 94% were deemed necessary. Only 1% of cases were considered not necessary for surgery, while 5% were rated uncertain. The situation was similar in 1999; the decision to refer for CABGS was considered appropriate in all but one case. Again, 95% of patients referred for surgery were considered to be necessary recipients of CABGS, in 3% the decision was termed uncertain, and 2% of cases were deemed unnecessary (Table 4.7).

In 1999, we sought to evaluate those who received necessity scores < 7; three patients had contraindications for surgery and 11 had chest pain of uncertain origin or congestive heart failure. Most patients had 2 vessel or diffuse disease. Further, this population was significantly older as compared to those patients deemed to be necessary recipients (Table 4.8).

Table 4.7 **Changes in the Appropriateness/Necessity 1995/1999**

Appropriateness	CABGS Referred 1995 (N=391)	CABGS Referred 1999 (N= 517)
Score 7-9 (Appropriate)	384 (98.2%)	488 (98.3%)
Score 4-6 (Indeterminate)	7 (1.8%)	8 (1.5%)
Score 1-3 (Not Appropriate)	0	1 (0.2)
Necessity		
Score 7-9 (Necessary)	368 (94.2%)	491 (94.9%)
Score 4-6 (Indeterminate)	17 (4.3%)	17 (3.3%)
Score 1-3 (Not Necessary)	6 (1.5%)	9 (1.7%)

Table 4.8 **Clinical Characteristics of CABGS Referral Cohort by RAND Necessity, 1999**

Rand Criteria for CABGS	Necessary for CABGS Therapy (7-9) (n=491)	Indeterminate for CABGS (4-6) (n=17)	Not Necessary for CABGS (1-3 or no code) (n=9)
Age	62.1	61.8	71.6
Sex (Male)	376 (76.6%)	15 (88.2%)	8 (88.9%)
Angina Class			
1			
2	16 (3.3%)	3 (17.6%)	6 (66.7%)
3	192 (39.1%)	10 (58.8%)	1 (11.1%)
4A	23 (4.7%)	2 (24.5%)	
4B	98 (20.0%)	1 (0.2%)	
4C	130 (26.5%)		
Other	32 (6.5%)	1 (5.9%)	2 (22.2%)
Coronary Anatomy			
Left Main	95 (19.3%)		
3-vessel disease	324 (66.0%)	3 (17.6%)	6 (66.7%)
2-VD +PLAD	55 (11.2%)	6 (35.3%)	1 (11.1%)
2-VD – PLAD	16 (3.3%)	5 (29.4%)	2 (22.2%)
1-VD + PLAD	1 (0.2%)	1 (5.9%)	
1-VD – PLAD			
Other		2 (11.8%)	
Maximum Medical Therapy (Yes)	386 (78.6%)	9 (52.9%)	0

To examine underutilization of CABGS, in 1995 Fox et al. identified an additional 31 patients for whom CABGS was considered necessary according to RAND criteria but who were not referred. In 1999 researchers identified an additional 91 patients deemed necessary. In the 1999 cohort, 78 of these patients received coronary angioplasty. Technological advancement in the application of percutaneous transluminal coronary angioplasty (PTCA) now allows a more variable patient selection. Although PTCA is beyond the scope of this paper, a review of the literature and analyis of this patient population suggests that treatment with PTCA for these patients was an acceptable alternative. A comparison between the cardiovascular team and the research team decisions are presented in Table 4.9. Level of agreement was assessed using Cohen's Kappa Statistic and indicated good agreement (0.86).

Table 4.9 **Comparison of Decisions Between Cardiovascular Team and the Research Team for Annual Incidence Cohort of Coronary Artery Disease (n=1625); 1999**

PANEL		*Cardiovascular Team*		
		CABG Surgery	No CABG Surgery	TOTAL
RAND Criteria	CABG Surgery	508	91	599
	No CABG Surgery	9	1017	1026
	TOTAL	517	1108	1625

Pair wise comparisons	*Kappa (CI)*
(CV Team vs. Research)	0.86 (0.84-0.88)

4.5 CABGS Wait-times

In 1995, 338 CABG surgeries were completed, but 391 patients were referred for the service. Thus, the Cardiac Care Program operated on an annual deficit of 53 surgeries. The waiting list increased by 20% throughout the study year. The average waiting time for CABGS among the patients referred for surgery during the study period was 33 days (SD=63.5). Using Naylor's priority scores, Table 4.10 documents the priority scores for these patients and corresponding proportions waiting less than maximum suggested time; indicating that 47% of all patients received surgery within recommended waiting time. However, it is of interest to note that patients prioritized to delayed elective (6 months) were most likely to receive surgery within a recommended time frame (75%). Fifty percent of patients in the elective category (6 weeks) received surgery within the recommended wait time while 64% of patients in the semi-urgent category (14 days) were promptly treated. However, those in emergent or very urgent categories were not likely to receive surgery in time (23 and 24% respectively). Figures 4.1 and 4.2 present Kaplan Meier life plots for this population demonstrating this trend.

In the later cohort, 1999, 517 patients were referred for revascularization and 434 CABG surgeries were undertaken. Thirty-nine (39)% of all clients received service within recommended wait time. Only 20% of 24 patients in the emergent priority received surgery within the recommended 24 hours. Thirty (30)% of clients in the very urgent category (less than 72 hours), whilst 49% of those in the urgent category (< 2 weeks) received surgery within the recommended waiting time. Seventy-one (71)% of patients in the semi-urgent group underwent CABGS within the recommended time frame. In the short-elective class (n=160), 55 patients (34.4%) had CABGS within the recommended 3 month waiting period. Finally, 17 of 41 (41%) patients in the delayed elective category underwent CABGS within the advised 6 months.

Patients were most likely to receive service on time in the urgent and semi-urgent category and were least likely to be done on time when asigned to the immediate or very urgent categories. Although patients differed in waiting times, there were no other statistically significant distinctions between those receiving surgery and those who remained waiting in terms of demographics, symptoms, or outcomes (Figures 4.3 and 4.4).

In 1999, the average waiting time for surgery was 86.9 days following referral (sd=156.5) while the median waiting time was 17 days. The greatest deterioration in waiting times occurred in those patients designated to the delayed elective priority. In consideration of utilization data, it is likely that the lowered threshold for CA access, has resulted in decreased efficiency in the elective category of patients.

Table 4.10 Changes in the Priorities 1995/1999

Priority	Waiting Time	N – 1995	Received Surgery Within Recommended Waiting Time (%)	N – 1999	Received Surgery Within Recommended Waiting Time (%)
1	< 24 hours	31	7 (23%)	24	5 (20.8%)
2	< 72 hours	122	30 (24%)	141	42 (29.8%)
3	< 2 weeks	87	56 (64%)	68	33 (48.5%)
4	< 6 weeks	98	49 (50%)	59	42 (71.2%)
5	< 6 months	53	40 (75%)	201	71 (35.3%)
TOTAL		391	182 (46.5%)	493*	193 (39.1%)

* 24 patients did not receive a priority score; they did not have angina

Figure 4.1 **Kaplan-Meier Life Plot A; 1995**

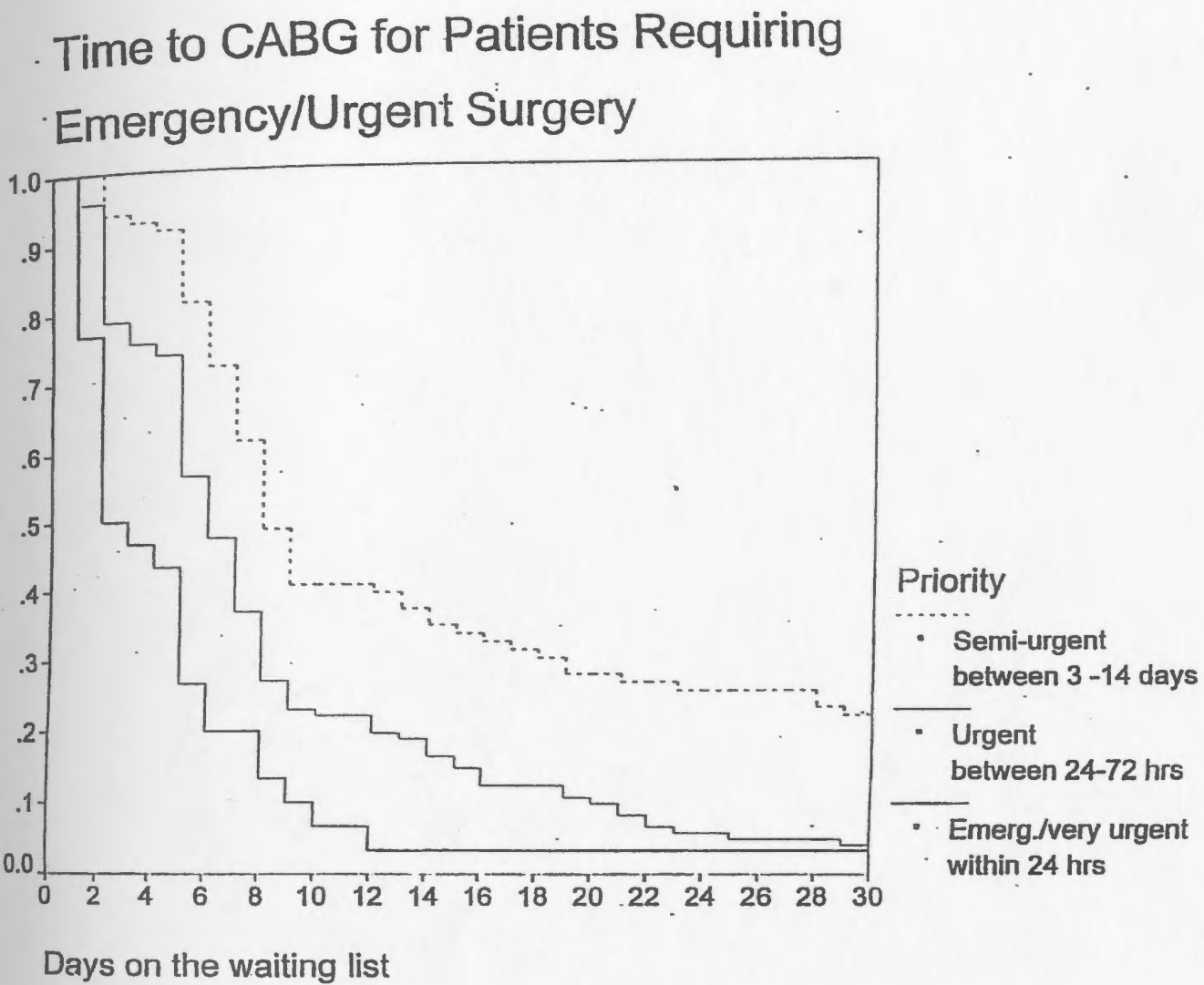


Figure 4.2 Kaplan-Meier Life Plot B; 1995

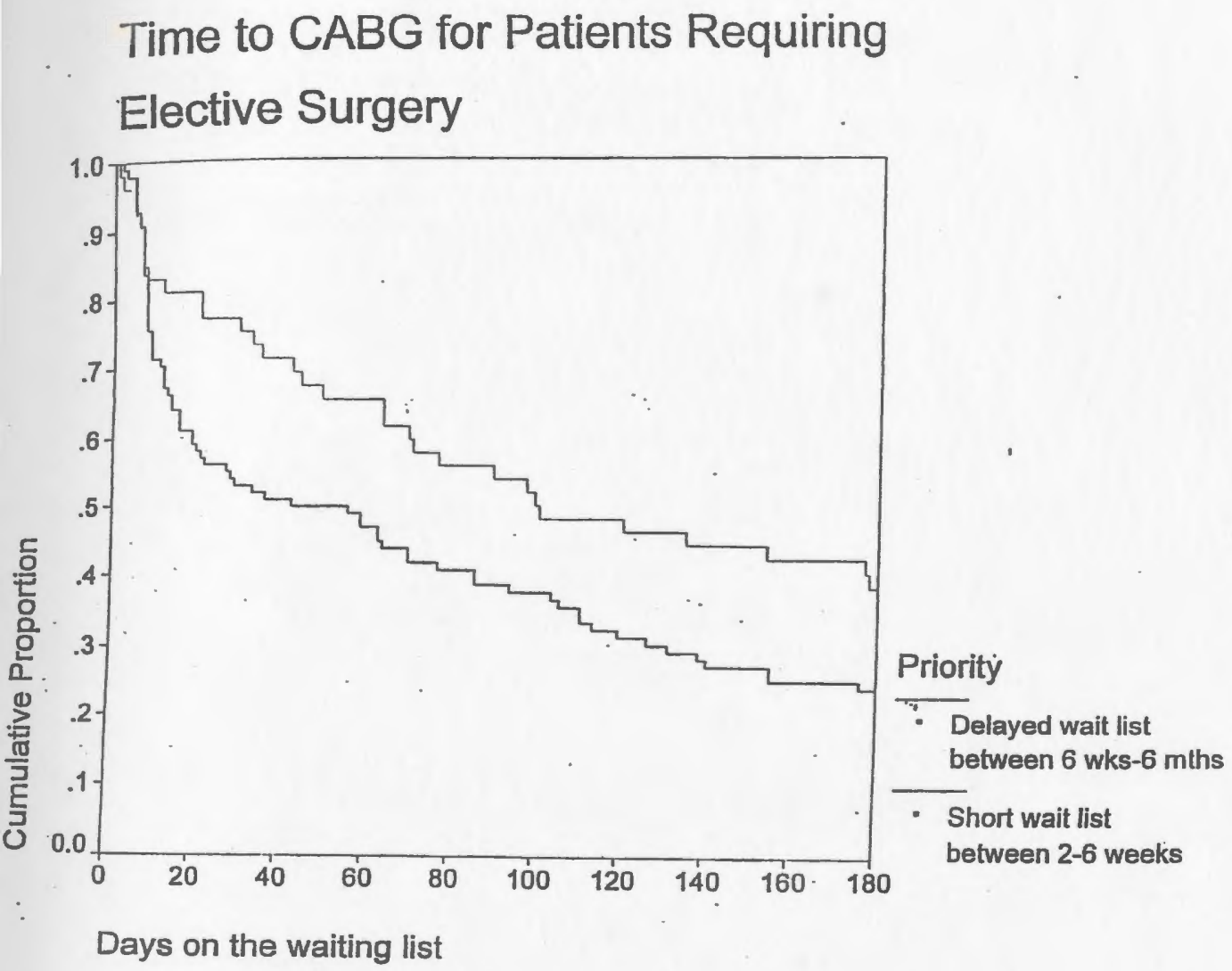


Figure 4.3 **Kaplan-Meier Life Plot A; 1999**

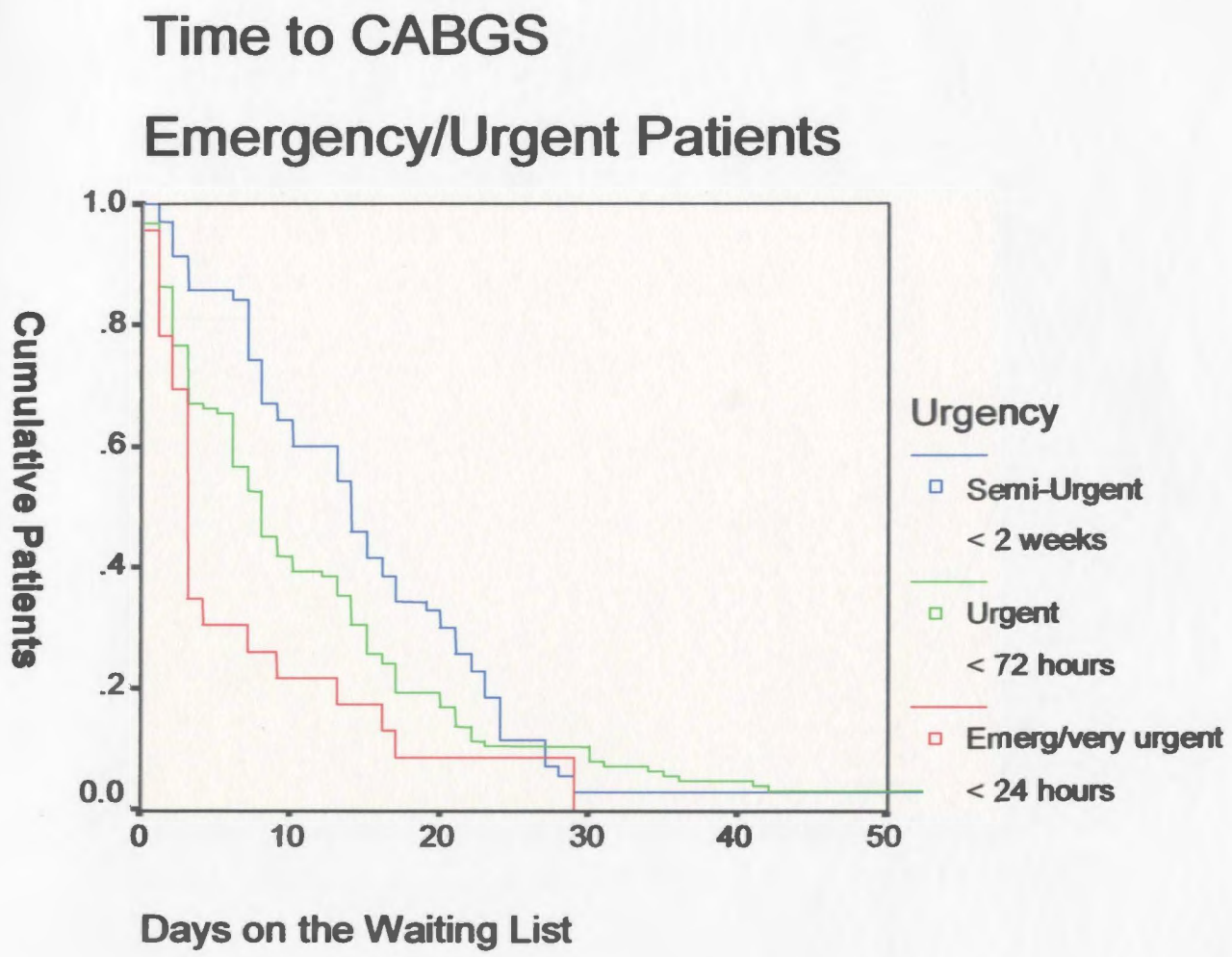
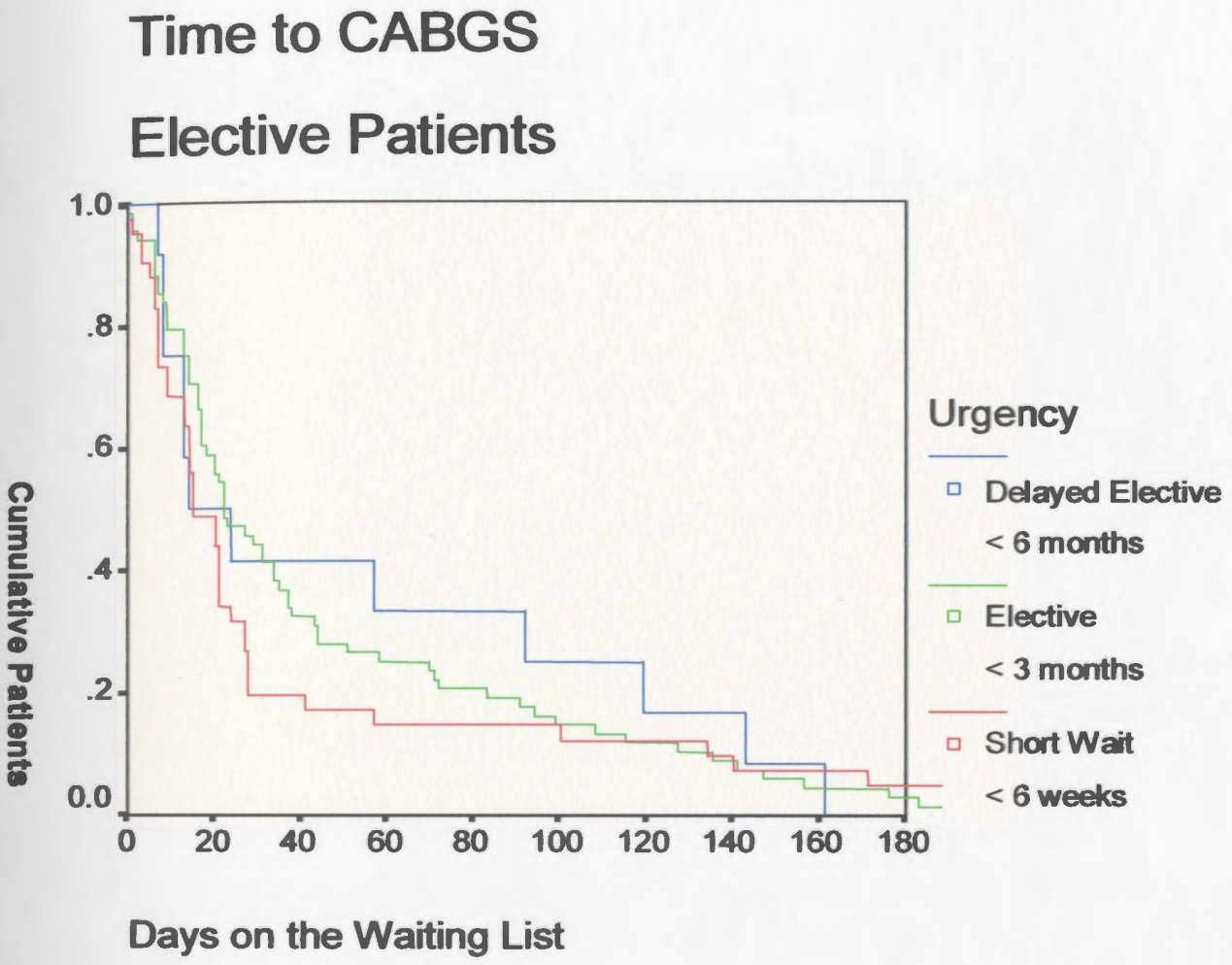


Figure 4.4 **Kaplan-Meier Life Plot B; 1999**



4.6 The Waiting List

As previously indicated, although 517 patients were referred for CABG surgery in 1999, only 434 surgeries were completed, an annual deficit of 83 surgeries. In the latter cohort, 7 patients died while awaiting surgery and 2 were removed from the list due to worsening clinical status. Hence, at the end of the study, 267 patients were on the waiting list for CABG surgery; an increase of almost 30% over the study period. Furthermore, it is of interest that researchers noted a change in clinical symptom as indicated by increasing severity of angina in another 28 patients who were waiting for surgery.

4.7 Quality of Care

In 1995, the median length of stay was 7 days. Factors influencing length of stay were recorded and are reported in Table 4.11. While mortality and morbidity rates were comparable to findings of other Canadian studies, ventilation greater than 3 days was the most frequent complication (7.7%). Eleven patients died post-operatively (3.3%).

In 1999, the post-operative length of stay (LOS) ranged from 1 through 135 days while the median LOS was again 7 days. Patients were followed until discharge. Fifteen (3.5%) patients died post-operatively (Table 4.11). Again, ventilatory assistance greater than 3 days was the most common cause with 5.3% of patients having this complication. Many (56%) of patients experienced some form of morbidity related to the CABG surgery; atrial fibrillation, pleural effusion, anemia, and confusion being the most common (Table 4.12).

Table 4.11 Post-operative Complication Rates 1995/1999

Complication	*1995 N=338 n (%)*	*1999 N=434 n (%)*	*Probability*
Re-operation	9 (2.7%)	10 (2.3)	NS
Ventilatory Assistance > 3 days	26 (7.7%)	23 (5.3)	< 0.05
Cardiac Arrest	8 (2.4%)	1 (0.2)	< 0.05
Myocardial Infarction	4 (1.2%)	9 (2.1)	NS
Sternal Wound Infection	15 (4.4%)	11 (2.5)	0.056
Groin/Leg Wound Infection	18 (5.3%)	12 (2.8)	<0.05
Mediastinitis	6 (1.8%)	3 (0.7)	NS
Stroke	2 (0.6%)	11 (2.5)	< 0.05
Arrhythmia requiring Pacemaker	10 (3.0%)	4 (0.9)	< 0.05
Arrhythmia	6 (1.8%)	2 (0.5)	NS
Acute Renal Failure requiring Dialysis	8 (2.4%)	3 (0.7)	< 0.05
Death	11 (3.3%)	15 (3.5)	NS

Table 4.12 Other Common Complications of CABGS Cohort; 1999

Complication	*n (%)*
Atrial Disturbances	106 (24.4)
Ventricular disturbances (arrhythmias)	11 (2.5)
Pleural effusion/pericardial rub	54 (12.4)
Post-operative anemia	21 (4.8)
Pneumonia	12 (2.8)
Pneumothorax	6 (1.4)
Pericarditis	10 (2.3)
Thromboembolism	6 (1.4)
Fluctuating glucose/early onset diabetes	11 (2.5)
Edema	9 (2.1)
Other respiratory problems	22 (5.1)
Signs of infection	14 (3.2)
Nausea/weakness/loss of vision	15 (3.5)
Seizures	4 (0.9)
Gastrointestinal problems	16 (3.7)
Urogenital problems	10 (2.3)
Hypotension	8 (1.8)
Renal insufficiency	8 (1.8)
Pain/discomfort	6 (1.4)
Confusion/ mental health issues	20 (4.6)
Other	22 (5.1)

4.8 Benchmarking the Need for CABGS

4.81 Fluctuation in Utilization

In 1999/2000 the annual growth in CA was 3.3% but the growth in those referred for CABGS was 6.0% (Table 4.13). This was influenced by inclusion of patients who had repeat coronary angiographies while waiting for CABGS and also by a reduction in the rate of PTCA from the previous year. The number of CABGS actually performed was less than the number referred and the wait list predictably increased. In comparison, in 2000/2001 the number of CABGS performed exceeded the number referred and the wait list actually decreased. However, the following year, referrals rose dramatically (14%) and again exceeded performance. Table 4.13 documents the 4 year trends in cardiac revascularization and waiting lists. The ability of the Cardiac Program to provide effective emergent care is probably influenced by the size of the waiting list. Fifty (50) additional CABGS will need to be performed each year to eliminate the waiting list within 5 years.

4.82 Annual Need and Future Predictions

From 1995 to 1999, there has been a shift to less acutely ill patients referred for CA and for CABGS. While the procedures were necessary, patients were less symptomatic. This shift to the less acutely ill was facilitated by a growth in PTCA. In 1998/99, the volume of PTCA used to treat the less ill patients had been related to the limited availability of revascularization surgery. Historically, the ratio of catheterization to CABGS referral has been consistent, demonstrating that as access to CA increases, the demand for CABGS also rises. There has been an 8% annual growth of CABGS referrals from 1994-2001.

Given that the objective criteria and the cardiovascular team decisions were similar, the cardiology referal rate for CABGS is a good proxy for the need of CABGS. Based on the 1999

study, we predicted that 691 surgeries/year would be required to meet community demands in 2001 (Table 4.14). However, 717 surgeries were actually referred and 20 patients were added to the waiting list. The diference between actual and predicted need makes benchmarking for the future unreliable. Comparison of clinical practice in 1995 and 1999 demonstrated that assumptions continue to change. Case mix for CA referral changed and patients with less severe symptoms were referred for CABGS. Indications for PTCA + stenting changed and utilization for this procedure increased substantially. From 1999, proportions referred for CABGS increased from 26% to 30% in 2001 (Table 4.13), while proportions referred for PTCA decreased from 29 to 23%.

Demonstrating continued flux of CABGS in utilization and demand, the researchers fear that assumptions cannot be maintained. Benchmarking data in a time of health care instability is not appropriate. Instead, the study indicates that physicians are appropriately and necessarily applying services. Therefore, it is by this means that govenrment should meet future demand.

Table 4.13 Coronary Revascularization Utilization+

	1998	1999	2000	2001
Coronary Catheterization	2196	2269	2258	2389
Referred CABG %	578 (26)	613 (27)	628 (28)	717 (30)
PTCA %	631 (29)	536 (24)	529 (23)	550 (23)
CABG performed	437	473	641	626
CABG Waiting List	227	308	223	243
Annual Growth in **CA (%)** **CABG (%)** **PTCA (%)**	 9.2* 12.0* 39.0*	 3.3 6.0 -15.1	 -0.5 2.4 -1.3	 5.8 14.2 4.0

+ Includes patients who had repeat CA while on CABGS waiting list

- Derived from increase between 1995 and 1999

Table 4.14 Annual Need for CABGS Based on 1999 Data

	1994/95	1998/99	1999/00	2000/01	2001/02
Referred for CABGS	391	517	517	517	517
Annual growth (8%)	NA	NA	41	83	124
Elimination of waiting list	NA	50	50	50	50
Predicted Need per year	462	567	608*	650*	691*
Need per 1000 population+	1.15	1.41	1.51	1.62	1.72

* Actual referrals were 613, 628, and 717 respectively

\+ Need/ population of Newfoundland in 1999

Calculations derived:

Using # of Patients referred in 1999 cohort	517
Increasing by 8% to 1999/00 (517*1.08)	41
Consideration of the waiting list	50
Predicted Need	608
Based on Population in 1999 (402,000)	1.51/1,000

CHAPTER V

Discussion

5.1 Introduction

This study has demonstrated that physician decision-making for CABGS continues to be appropriate. We have noted changes in utilization over the study years, making estimation of the need for CABGS in coming years difficult. Despite an increase in resources, access to CABGS continues to be inadequate.

This study has several limitations. Firstly, using an abstraction form compiled from a combination of secondary data sets has limitations. The selection of which data to collect and the quality of the data gathered was predetermined (53). Furthermore, previously discussed problems in the RAND technique and data quality must be considered.

Two research personnel gathered information prospectively from medical charts, and reports using patient and physician clarification when required. Hence, most of the data was compiled using information from numerous medical staff personnel and from a variety of disciplines. As a result, the quality of data must be variable and problems are largely undetectable (53). Although there were few complications in assessing the information, a number of variables were noted to be unreliably reported. For example, tests of ischemic risk were necessary in the application of Naylor's priority score. Although a common procedure, most cardiac patients did not require the test and if completed, the results were often ambiguous or outdated. A further weakness results from evidence suggesting variability in the interpretation of coronary angiography (79).

Scores were easily determined for most patient scenarios, however discrepancies between researchers still existed. Nevertheless, inter-rater reliability was high (Kappa statistic=0.92).

Using the objective criteria, we have excluded patient preferences, as well as other factors that may have been revealed through patient-physician consultations. For example, in 1995, despite being offered surgery out of the province, none of the 41 patients who had waited > 12 months opted for this management (108).

5.2 Limitations of Benchmarking

Benchmarking the population-based need for CABG surgery is unreliable. There is an abundance of medical literature targeted to cardiologists who want clinical benchmarking data, but recent evidence suggests that accurate, real-time, national and regional benchmarks that integrate cost and clinical quality are scarce (132).

In order to determine population based need, several assumptions are necessary. It is important to quantify what proportion of the population is at risk. Here, we have assumed that all patients with critical coronary artery disease are identified. This poses several restrictions. Firstly, a proportion of patients are asymptomatic and thus, will not present to the hospital setting. Furthermore, all patients requiring cardiac catheterizations must be referred to the Health Sciences Centre and catheterization should be provided in a timely manner. This requires that family physicians promptly and accurately assess prospective patients. The need for CABG surgery is based on the identification of critical coronary artery disease through coronary angiography, and it is this factor that most accurately reflects the need for CABG surgery. By increasing cardiac catheterization capacity, the need for CABG surgery also increases (137). Despite increased utilization, inappropriate angiography use remained low and thus, appropriate diagnosis of CAD has been assumed. The average patient waited only 7 days for cardiac catheterization and the rate of inappropriate use was only 3.9%. As previously indicated, NL has a high prevalence of CAD relative to other Canadian provinces and thus, we would expect high

rates of angiography in this setting. In addition to this, the identification of CAD may be inaccurate. Gould demonstrated up to a 50% error rate in EST (exercise stress testing) and noted that 25% of angiographies improperly diagnose CAD (45,46). However, coronary angiography remains the gold standard for cardiac diagnostics (124). Leape and colleagues have suggested that discrepancies in diagnosing CAD have minimal consequences in the application of RAND criteria (79). Entry into the study was determined by diagnosis of critical coronary artery disease, which was precisely defined through cardiac angiography. Given that cardiac catheterization reports include an assessment by a radiologist and cardiologist, the researchers had little difficulty in identifying the study population. Moreover, the study sample is quite large and it is unlikely that this variable was substantially biased.

5.21 Will access to CA and CABGS change?

While inappropriate usage of CA has remained reasonably low, the proportion of patients diagnosed with CAD has remained stable. With the opening of a second catheterization laboratory, increased angiography utilization in coming years will occur, which will result in an increase in CABGS referral. Using utilization data, we have estimated this increase will be approximately 8% per annum. However, continued monitoring will be necessary to ensure inappropriate utilization of CA is detected.

We have identified that CABGS is applied to patients appropriately using the RAND criteria. Ninety-five percent (95%) of surgeries performed were necessary and the cardiovascular team had almost perfect agreement with the objective scores. This evidence implies that current clinical decision-making is indeed a reliable tool by which to benchmark need. Increasing utilization of CABGS from a relatively low baseline rate would not be expected to be associated with a large increase in unnecessary surgeries. However, when supply equals

demand, it is more likely that over utilization will occur and it will be necessary to monitor any inappropriate usage. Further, quality of care may be compromised. Demonstrating good quality of care and standard morbidity rates improves satisfaction with the service. We have established that NL is currently providing good quality of care, as indicated by length of stay, mortality and morbidity. These findings were comparable with other results from Canadian provinces and benchmarking studies (44,54,93,104). In the circumstance of restricted access to CABGS in NL, over utilization is unlikely whilst under utilization will inevitably occur. However, setting a future benchmark is difficult because the degree of underutilization is uncertain. Increased demand for CA and the advent of PTCA with stenting further complicates the scenario. In times of increasing access to new technologies, it will continue to be difficult to set a benchmarking rate.

5.3 Issues Arising From the Study

5.31 Newfoundland and Labrador's Cardiac Care Program

Funding health care places considerable financial burden on government, particularly in a nation such as ours, whereby health care is deemed a constitutional right to every citizen. In attempts to control increasing financial burden, the health care system in many provinces is faced with reduced funding and resource cutbacks. Newfoundland and Labrador is no exception. Dispersely populated, it is faced with the overwhelming task of providing health services in a reasonably timely and effective manner to a scattered population. An investigation completed in the United States found that there were no data to indicate that outcomes were related to specific surgeon volume. However, centralizing the provision of coronary revascularization is believed to enhance performance and delivery of service due to a best performer model (8). Indeed, Newfoundland and Labrador's outcome measures have proved comparable to other provinces

(44,54). This type of system, through a wealth of knowledge and resources, enables the cardiovascular team to handle more difficult cases, further encouraging increased demand for CABGS.

5.32 The balance between supply and demand

The current study demonstrated that demand continued to exceed supply. While the CV panel referred 517 patients, only 434 surgeries were completed in 1999; hence, running an annual deficit of 83 surgeries. Using RAND criteria, researchers have identified additional clients who may have benefited from CABG surgery. With this noted, it is important to remember that demand is ultimately based upon the use of the cardiac catheterization laboratory. By enhancing access to this service, it is likely that more patients will be identified to have critical coronary artery disease, and in turn, more patients will require CABG surgery. However, continued fluctuations in usage are associated with changing referral rates as doctors attempt to overcome barriers to revascularization. Nonetheless, failure to increase CABGS utilization at a time of growth in CA will lead to unacceptable deterioration in waiting times for surgery.

5.33 Waiting list management

Using Naylor priority scoring, we have shown that although wait times are often exceeded, the time to surgery curves suggest that the CV panel was indeed prioritizing patients appropriately. Such evidence implies that clinical practice was appropriate and that the cardiovascular team was appropriate in its clinical decision-making. Nevertheless, poor access to the service has lengthened wait times particularly for elective patients and demand was not being met. In a system of managed delay such as this, when demand exceeds capacity, it is much more likely the more urgent cases are bypassed (66). This is reiterated in other Canadian investigations (66,99,102,103,104). Thus, we have reduced the ability to provide emergent care,

and this has considerable consequences in a queue-based system. To our knowledge, 28 patients had worsening symptoms prior to receiving treatment. Further, a total of 7 patients died while waiting for CABG surgery. Patients who continue to wait for surgery undergo considerable physical stress and are usually not able to work. This constitutes both familial and societal economic burdens. In addition, bed blocking is of paramount importance since some of these clients were unable to leave hospital and thus occupied acute care beds. Compounding this issue, patients who wait more than 6 months are required to undergo re-catheterization and this, of course, occupies the catheterization laboratory unnecessarily. Although such findings are similar to previous results (42), this evidence does indicate considerable issues with managed delay. Previous attempts at front load reduction of the waiting list or a reduction in the rate of referral have had little success due to considerable financial difficulties and ethical concerns (91). NL has attempted to resolve this issue by offering candidates financial assistance and opportunity to receive surgery in other Canadian provinces. Only 1 of 41 who had waited > 1 year opted to participate, resulting in a failed campaign (25, 108). This undoubtedly leads to public concern and angst. With expected increasing demand in the coming years, it is unlikely that health care management will be able to provide service to all clients and thus, it becomes imperative to provide reasonable and objective wait-time goals.

5.34 Changing Clinical Practice

Although the RAND Canadian criteria for necessity identified an additional 91 patients for whom surgery was deemed necessary, 78 of these patients received revascularization in the form of PTCA + stenting. Because the literature base is dated, PTCA may have been appropriate treatment for these patients in light of increasing indications for PTCA and improved efficacy (5,23,37,41,115,118,124,135). It is the physician decision which most accurately reflects

changes in resources. This study has demonstrated that the referral rate by cardiologists is very accurate as compared to an objective scoring system.

5.35 Predicting Future Need

There is a steady and linear incline in the growth rate of the Canadian population. Statistics Canada estimates a population of almost 36 million by 2010 (52). Simultaneously, changing fertility trends and mortality rates have resulted in an increasing growth rate in the elderly population. It is important to consider that NL has a significant level of out-migration, but this has comprised mainly of the working young. Furthermore, it is possible that these people return to NL in their elder years. Utilization rates of coronary revascularization have risen in recent years and it is predicted that this trend will continue as the population ages.

Irrespective of this population shift, speculations by some researchers suggest that the need for revascularization should decrease in the coming years. Despite decades of use of revascularization to treat CAD, this treatment remains a non-permanent solution (41). Recent evidence suggests that CABGS only appears to be effective in patients with 3-vessel disease, when analysis is adjusted for other risk factors (83). Furthermore, when patients who had an acute MI are excluded, this benefit almost disappears. An overview of CABGS's effect on survival at 10 years demonstrated the advantage to be only 4 months, and that this benefit was largely confined to patients with left main CAD, a high operative risk score, and abnormal left ventricular function (141). Similarly, PTCA demonstrated no survival advantage compared to medical therapy and may have only modest value in symptom relief and patient preference (60). In addition, evidence from Holland suggests that the largest benefit can be achieved through primary prevention (22). The discovery and implementation of numerous primary preventative measures further suggests the need for CABGS should decrease. Public awareness has

heightened and it is likely that this should also reduce the prevalence of risk factors in the population. However, this may be offset by the increasing prevalence of diabetes, particularly in the aboriginal communities.

Dzavik suggests that the need for CABG will actually increase in the coming 10 years (36). Consistent with a growing population and an increasing proportion of the elderly, he suggests that this change in demographics will instead increase the prevalence of CAD in a proportional manner. Further, the under utilization of preventative pharmacology due to physician and patient factors will decrease their relevance. One study of over 3300 patients demonstrated a less than 7% rate of medication use. As well, the increasing numbers of survivors of MI's will increase the total number of patients who will eventually require revascularization (36). In addition, treatment with CABGS is not a cure, and hence, these people are often entered into the cyclic pattern of presentation, treatment, relief, and then worsening symptoms. Finally, CAD has been considered a disease of the western world. Studies in Asia suggest an alarming rise in prevalence of CV risk factors (52). It can only be anticipated that advancing global economies will heighten this effect (36).

In Newfoundland and Labrador, it is likely that in the next 10 years, improved primary prevention will be offset by growth in diabetes, better survival from MI, aging of the population, and better detection of critical CAD through increased CA utilization. Moreover, the indications for CABG surgery are expanding. To date, no intervention proves to be as effective for improving the quality of life for patients.

5.4 Comparison of Study Periods

The findings from the 1995 study completed by Fox et al. demonstrated that the application of CABG surgery was indeed appropriate and that the quality of care was good (42).

However, it found that wait times were not optimal and that not all necessary surgeries were completed. From a review of the population demographics, it became apparent that in the most recent study, patients receiving CABG surgery were less symptomatic as compared to previous findings (24% Class IVC angina as compared to 42% respectively) and that the indication for surgery was no longer overwhelmingly unstable angina (50% as compared to 74% in 1994/5). In 1999, 60% of patients had triple vessel disease, similar to 57% in 1995. A majority of clients in both time periods were in a low operative risk category (64% and 67% respectively), and only 4% of current cases were considered high risk in 1999 as compared to 10% in the 1995 study. These data were consistent with increased access to catheterization for patients diagnosed with stable angina syndromes requiring elective surgery.

Wait times did not improve over time. In 1995, researchers found that only 47% of patients received surgery within the appropriate time. In 1999, only 39% of patients received surgery within the recommended time period. Consistent with the hypothesis that demand exceeded supply, those patients in the urgent and semi-urgent category were least likely to be completed on time. Unfortunately, 107 patients remained on the waiting list throughout the study period.

Following the 1995 study, attempts were made by the Government of Newfoundland and Labrador and the Health Care Corporation of St. Johns to increase the capacity of the cardiac program (i.e., from the 1995 average of 10 to 12 procedures per week). Restructuring of the Cardiac Care Unit and Cardiovascular Intensive Care Unit have increased the number of available beds from 14 to 17 through a provision of capital funds (almost $1 million) and an appropriate increase in the annual operating budget ($2 million per year) (25). These funds allowed for the addition of a 2nd operating room in 1997. Eight additional beds were provided to

the coronary recovery ward and 3 additional nurse practitioners were hired. However, problems with the provision of perfusionists, intensive care unit beds, and adequate number of surgeons have prevented NL from achieving the target number of CABGS. During the 1999 study period, a nurse's strike exacerbated this problem and resulted in over 3 weeks of delayed surgeries. Thus, an average of only 8.4 surgeries per week were completed during the study period. These issues were addressed and by the end of the study period, new perfusionists were hired and the nurses' contract was renegotiated. In 2002, a second catheterization laboratory was opened to facilitate access to CA. However, Newfoundland and Labrador continues to combat issues with recruitment.

Predicted need for 2001 was 691 surgeries per year. It is obvious that Newfoundland and Labrador was failing to achieve this rate. In addition to this, the assumptions used to predict future benchmarks were unreliable and predispose to continued failure in matching supply and demand for CABGS. This failure to satisfy increased demand during recent years has continued to produce dissatisfied patients, media attention, and political controversy despite substantial efforts to alleviate this crisis situation (108).

5.5 Summary

Using similar practice guidelines and research infrastructure over two study periods, separated by 4 years, external validity was maximized. We have demonstrated that Newfoundland and Labrador was performing appropriate and necessary coronary revascularization, but despite prioritizing patients, access was limited. The governmental decision to fund the program based on the referral rate by cardiologists has been welcomed by the service provider. However, this rate has increased over time because of appropriate increased referral of stable angina for elective surgery. From the payer perspective, this

continued growth in need induces substantial stress on the provincial budget, and raises questions concerning capacity to pay for this demand. The fact that this growth rate is unpredictable creates even greater tensions. While delays in service provision may be a source of persistent frustration and dissatisfaction, patients waiting for CABGS are nevertheless at similar or reduced risk of morbidity and mortality as compared to other patients with a similar cardiac profile (79, 104).

The advent of a second cardiac catheterization laboratory and increased capacity to perform CABGS suggests that the rate of CABGS will continue to increase. This is appropriate at present because underutilization of CABGS in evident. Nonetheless, continued monitoring of utilization and case mix is necessary to ensure continued funding of CABGS at a rate appropriate to the capacity of the province to pay.

The government may rely on the cardiology referral rates as a reasonable means by which to benchmark need. Thus, interference with clinical decision-making will not be necessary until the disparity between objective need and demand widens.

CHAPTER VI

Conclusions and Recommendations

The government of Newfoundland and Labrador agreed to fund CABGS based upon predictions estimated from the 1995 study. However, the health care system was slow in providing the capacity to meet this demand; failing to achieve benchmarking rates. This resulted in continued disparity between supply and demand, leading to increases in the waiting list and waiting times. This failure was exacerbated by increased annual incident cases requiring revascularization. The current investigation sought to revisit these predictions and the assumptions on which they were based.

The initial benchmarks have proven unreliable due to 1) a growth in coronary angiography by higher referral rates and increased access, 2) earlier referrals for CABGS patients with less symptomatic disease, and 3) increased utilization of PTCA. Thus, revised benchmarking data must consider these facets in addition to the knowledge that NL has an increasing elderly population.

This report has demonstrated that a) the proportion of those diagnosed with critical CAD among those receiving angiography increased from 68% (1994/5) to 74% (1998/9), and b) the proportion of inappropriate catheterizations remained low (4%). Thus, increased utilization has not resulted in inappropriate use. CABG surgery had been appropriately and necessarily applied. The cardiovascular team had identified almost all patients for whom surgery was deemed necessary while almost all the applications of surgery were necessary. This evidence is consistent for both time periods under investigation, indicating acceptable clinical decision-making. Also highlighted in these findings, the identification of critical coronary artery disease is dependent upon cardiac catheterization utilization. Hence, it is likely that with an increasing

elderly population, and with earlier referrals for catheterization, so, too, the need for CABG surgery will increase. Considering the evidence, it is apparent that the referral rate by the cardiovascular team is currently a reasonable and cost-effective way in which to plan the funding for the CABGS program in NL. Physician decision best considers change in clinical practice and access to resources.

While the cardiovascular team in Newfoundland and Labrador has effectively prioritized patients, the demand has exceeded supply. Thus, considerable waiting list issues have resulted. It is apparent that patients deemed most urgent were least likely to receive surgery within the appropriate framework of time. However, current findings also suggested that increased need for CABGS was found in elective and more stable cases. This trend will further exacerbate the waiting list concerns.

The quality of care during these investigations has not changed and has been comparable to previously demonstrated Canadian findings. It can be inferred that increasing capacity has not affected the quality of service delivery in this province.

The rates of utilization have been determined and annual needs have been revised. We estimated annual need to be 1.72 surgeries/ 1,000 population > 20 yrs of age in 2001/2002. In addition to a reasonable reduction in the waiting list, 691 surgeries were predicted to meet demand. However, on review of utilization data, 717 surgeries were referred during this year and an additional 20 patients were added to the waiting list. Thus, the benchmarking data was unreliable. It remains questionable whether NL is capable of achieving these benchmarking rates in a climate of uncertainty and high personnel turnover. Utilization rates have continued to fluctuate and thus limit our ability to rely on assumptions.

In a climate of increasing demand in a universal health care system with a limited budget, it is vital that the health care profession continue to monitor and assess the provision of all coronary revascularization services to plan for the future. While continued assessment is required, the focus of future research should aim to clarify the appropriate rate of utilization of coronary angiography. A national database would aid in this assessment by reducing manpower and financial considerations while broadening possibilities for research and analysis. In a cross-sectional assessment, only 22% of questioned institutions had comprehensive cardiovascular information systems (132). It is imperative that all Canadian provinces follow suit and implement complementary databasing systems.

The issues within a system of care are diverse and complex. Economic, social, and political considerations are relevant. Long range planning and research, which provides a solid foundation for the decisions of today and tomorrow, are mandatory for the continued sustenance of Canada's Health Care system.

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Appendix A

CORONARY ARTERY BYPASS GRAFT SURGERY AND PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

Ratings of Appropriateness and Necessity by a Canadian Panel

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Elizabeth A. McGlynn, Ph.D.
Lucian L. Leape, M.D.
Lee H. Hilborne, M.D., M.P.H.
The Canadian Revascularization Panel
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The Canadian Revascularization Panel

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Arvind Koshal, M.D.
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RAND

Chapter 2 UNSTABLE ANGINA	NORMAL OR LOW RISK			MODERATELY HIGH RISK			VERY HIGH RISK			
	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	
SYMPTOMS ON MAXIMAL MEDICAL THERAPY										
A1. LEFT MAIN DISEASE (PROTECTED LEFT MAIN)										
1. Ejection fraction >35%	1 8 1 2 3 4 5 6 7 8 9 (9.0, 0.6, A)			1 2 6 1 2 3 4 5 6 7 8 9 (9.0, 0.8, A)			1 1 7 1 2 3 4 5 6 7 8 9 (8.0, 0.6, A)			(1- 9)
2. Ejection fraction 15-35%	1 1 7 1 2 3 4 5 6 7 8 9 (9.0, 0.7, A)			1 1 1 6 1 2 3 4 5 6 7 8 9 (9.0, 0.9, A)			1 1 1 6 1 2 3 4 5 6 7 8 9 (8.0, 0.8, A)			(10- 18)
3. Ejection fraction <15%	1 1 2 3 2 1 2 3 4 5 6 7 8 9 (8.0, 1.1, A)			1 1 1 2 2 2 1 2 3 4 5 6 7 8 9 (7.0, 1.3, I)			2 1 2 2 2 1 2 3 4 5 6 7 8 9 (6.0, 1.2, I)			(19- 27)
A2. LEFT MAIN DISEASE (UNPROTECTED LEFT MAIN)										
1. Ejection fraction >35%	1 8 1 2 3 4 5 6 7 8 9 (9.0, 0.1, A)			4 5 1 2 3 4 5 6 7 8 9 (9.0, 0.4, A)			1 2 5 1 1 2 3 4 5 6 7 8 9 (8.0, 0.6, A)			(28- 36)
2. Ejection fraction 15-35%	1 1 7 1 2 3 4 5 6 7 8 9 (9.0, 0.3, A)			2 2 5 1 2 3 4 5 6 7 8 9 (9.0, 0.7, A)			3 1 4 1 1 2 3 4 5 6 7 8 9 (8.0, 0.9, I)			(37- 45)
3. Ejection fraction <15%	2 2 3 2 1 2 3 4 5 6 7 8 9 (8.0, 0.9, A)			1 2 3 1 2 1 2 3 4 5 6 7 8 9 (7.0, 1.0, I)			1 3 2 1 1 1 1 2 3 4 5 6 7 8 9 (6.0, 1.2, I)			(46- 54)
B. THREE VESSEL DISEASE										
1. Ejection fraction >35%	3 6 1 2 3 4 5 6 7 8 9 (9.0, 0.3, A)			4 5 1 2 3 4 5 6 7 8 9 (9.0, 0.4, A)				1 5 3 1 2 3 4 5 6 7 8 9 (7.0, 0.6, A)		(55- 63)
2. Ejection fraction 15-35%	1 3 5 1 2 3 4 5 6 7 8 9 (9.0, 0.6, A)			2 3 4 1 2 3 4 5 6 7 8 9 (8.0, 0.7, A)				1 1 6 1 1 2 3 4 5 6 7 8 9 (7.0, 0.4, A)		(64- 72)
3. Ejection fraction <15%	2 3 3 1 1 2 3 4 5 6 7 8 9 (7.0, 0.8, A)				1 2 3 4 1 2 3 4 5 6 7 8 9 (7.0, 0.9, I)				4 2 2 1 1 2 3 4 5 6 7 8 9 (6.0, 0.9, I)	(73- 81)
C. TWO VESSEL DISEASE WITH PROXIMAL LEFT ANTERIOR DESCENDING INVOLVEMENT										
1. Ejection fraction >35%		1 5 3 1 2 3 4 5 6 7 8 9 (8.0, 0.4, A)			4 3 2 1 2 3 4 5 6 7 8 9 (8.0, 0.7, A)				3 5 1 1 2 3 4 5 6 7 8 9 (7.0, 0.4, I)	(82- 90)
2. Ejection fraction 15-35%		3 2 4 1 2 3 4 5 6 7 8 9 (8.0, 0.8, A)			2 2 3 2 1 2 3 4 5 6 7 8 9 (8.0, 0.9, A)				2 2 4 1 1 2 3 4 5 6 7 8 9 (7.0, 0.8, I)	(91- 99)
3. Ejection fraction <15%		1 3 2 2 1 1 2 3 4 5 6 7 8 9 (7.0, 1.0, I)			4 4 1 1 2 3 4 5 6 7 8 9 (7.0, 1.1, I)				1 5 2 1 1 2 3 4 5 6 7 8 9 (5.0, 0.9, I)	(100-108)

Necessity scale: 1-Procedure is clearly not necessary; 5-Procedure might be necessary; 9-Procedure is clearly necessary.

Chapter 2 UNSTABLE ANGINA	NORMAL OR LOW RISK			MODERATELY HIGH RISK			VERY HIGH RISK			
	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	
D. TWO VESSEL DISEASE WITHOUT PROXIMAL LEFT ANTERIOR DESCENDING INVOLVEMENT										
1. Ejection fraction >35%		4 5 1 2 3 4 5 6 7 8 9 (8.0, 0.4, A)			1 3 5 1 2 3 4 5 6 7 8 9 (8.0, 0.6, A)				2 6 1 1 2 3 4 5 6 7 8 9 (7.0, 0.3, A)	(109-117)
2. Ejection fraction 15-35%		1 4 4 1 2 3 4 5 6 7 8 9 (7.0, 0.6, A)			1 4 4 1 2 3 4 5 6 7 8 9 (7.0, 0.7, A)				1 2 5 1 1 2 3 4 5 6 7 8 9 (7.0, 0.6, I)	(118-126)
3. Ejection fraction <15%		2 3 3 1 1 2 3 4 5 6 7 8 9 (6.0, 0.8, I)				3 3 2 1 1 2 3 4 5 6 7 8 9 (6.0, 0.8, I)			1 2 4 1 1 1 2 3 4 5 6 7 8 9 (6.0, 0.8, A)	(127-135)
E. SINGLE VESSEL DISEASE - PROXIMAL LEFT ANTERIOR DESCENDING										
1. Ejection fraction >35%			1 5 3 1 2 3 4 5 6 7 8 9 (8.0, 0.4, A)			4 3 2 1 2 3 4 5 6 7 8 9 (8.0, 0.7, A)			4 2 3 1 2 3 4 5 6 7 8 9 (7.0, 0.8, I)	(136-144)
2. Ejection fraction 15-35%			2 5 2 1 2 3 4 5 6 7 8 9 (8.0, 0.4, A)			1 4 2 2 1 2 3 4 5 6 7 8 9 (7.0, 0.8, A)			2 3 1 3 1 2 3 4 5 6 7 8 9 (6.0, 1.0, I)	(145-153)
3. Ejection fraction <15%			2 4 3 1 2 3 4 5 6 7 8 9 (7.0, 0.6, A)			2 2 2 3 1 2 3 4 5 6 7 8 9 (7.0, 1.0, I)			1 3 1 3 1 1 2 3 4 5 6 7 8 9 (6.0, 1.1, I)	(154-162)
F. SINGLE VESSEL DISEASE - ANY VESSEL OTHER THAN PLAD										
1. Ejection fraction >35%			4 4 1 1 2 3 4 5 6 7 8 9 (8.0, 0.6, A)			1 5 2 1 1 2 3 4 5 6 7 8 9 (7.0, 0.6, A)			1 4 3 1 1 2 3 4 5 6 7 8 9 (6.0, 0.7, I)	(163-171)
2. Ejection fraction 15-35%			1 4 3 1 1 2 3 4 5 6 7 8 9 (7.0, 0.7, A)			1 1 4 2 1 1 2 3 4 5 6 7 8 9 (7.0, 0.8, A)			1 1 3 3 1 1 2 3 4 5 6 7 8 9 (6.0, 0.9, I)	(172-180)
3. Ejection fraction <15%			2 3 1 3 1 2 3 4 5 6 7 8 9 (6.0, 1.0, I)			1 3 1 1 3 1 2 3 4 5 6 7 8 9 (6.0, 1.3, I)			1 1 1 4 1 1 1 2 3 4 5 6 7 8 9 (6.0, 1.0, I)	(181-189)

Necessity scale: 1=Procedure is clearly not necessary; 5=Procedure might be necessary; 9=Procedure is clearly necessary.

Chapter 2 UNSTABLE ANGINA	NORMAL OR LOW RISK Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	MODERATELY HIGH RISK Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	VERY HIGH RISK Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	
SYMPTOMS ON LESS THAN MAXIMAL MEDICAL THERAPY										
A1.LEFT MAIN DISEASE (PROTECTED LEFT MAIN)										
1. Ejection fraction >35%	1 1 1 6 1 2 3 4 5 6 7 8 9 (9.0, 1.0, A)			2 3 4 1 2 3 4 5 6 7 8 9 (8.0, 1.3, A)						(190-198)
2. Ejection fraction 15-35%	1 1 2 5 1 2 3 4 5 6 7 8 9 (9.0, 1.2, A)			1 1 1 3 3 1 2 3 4 5 6 7 8 9 (8.0, 1.7, A)						(199-207)
3. Ejection fraction <15%	1 1 1 2 2 2 1 2 3 4 5 6 7 8 9 (7.0, 1.7, I)									(208-216)
A2.LEFT MAIN DISEASE (UNPROTECTED LEFT MAIN)										
1. Ejection fraction >35%	1 8 1 2 3 4 5 6 7 8 9 (9.0, 0.1, A)			1 2 6 1 2 3 4 5 6 7 8 9 (9.0, 0.4, A)			1 3 3 2 1 2 3 4 5 6 7 8 9 (8.0, 0.8, A)			(217-225)
2. Ejection fraction 15-35%	2 7 1 2 3 4 5 6 7 8 9 (9.0, 0.2, A)			1 3 5 1 2 3 4 5 6 7 8 9 (9.0, 0.6, A)			2 3 2 2 1 2 3 4 5 6 7 8 9 (7.0, 0.9, A)			(226-234)
3. Ejection fraction <15%	1 2 4 2 1 2 3 4 5 6 7 8 9 (8.0, 0.7, A)			1 1 1 4 2 1 2 3 4 5 6 7 8 9 (8.0, 0.9, A)						(235-243)
B. THREE VESSEL DISEASE										
1. Ejection fraction >35%	5 3 1 1 2 3 4 5 6 7 8 9 (7.0, 0.6, A)			4 1 3 1 1 2 3 4 5 6 7 8 9 (7.0, 1.0, I)						(244-252)
2. Ejection fraction 15-35%	2 2 4 1 1 2 3 4 5 6 7 8 9 (8.0, 0.8, A)			2 1 2 3 1 1 2 3 4 5 6 7 8 9 (7.0, 1.1, I)						(253-261)
3. Ejection fraction <15%										(262-270)
C. TWO VESSEL DISEASE WITH PROXIMAL LEFT ANTERIOR DESCENDING INVOLVEMENT										
1. Ejection fraction >35%		3 5 1 1 2 3 4 5 6 7 8 9 (7.0, 0.6, I)				1 1 3 3 1 1 2 3 4 5 6 7 8 9 (6.0, 0.9, I)				(271-279)
2. Ejection fraction 15-35%	1 1 3 2 2 1 2 3 4 5 6 7 8 9 (6.0, 1.0, I)									(280-288)
3. Ejection fraction <15%										(289-297)

Necessity scale: 1-Procedure is clearly not necessary; 5-Procedure might be necessary; 9-Procedure is clearly necessary.

Chapter 2 UNSTABLE ANGINA	NORMAL OR LOW RISK			MODERATELY HIGH RISK			VERY HIGH RISK			
	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	
D. TWO VESSEL DISEASE WITHOUT PROXIMAL LEFT ANTERIOR DESCENDING INVOLVEMENT										
1. Ejection fraction >35%										(298-306)
2. Ejection fraction 15-35%										(307-315)
3. Ejection fraction <15%										(316-324)
E. SINGLE VESSEL DISEASE - PROXIMAL LEFT ANTERIOR DESCENDING										
1. Ejection fraction >35%										(325-333)
2. Ejection fraction 15-35%										(334-342)
3. Ejection fraction <15%										(343-351)
F. SINGLE VESSEL DISEASE - ANY VESSEL OTHER THAN PLAD										
1. Ejection fraction >35%										(352-360)
2. Ejection fraction 15-35%										(361-369)
3. Ejection fraction <15%										(370-378)

Necessity scale: 1-Procedure is clearly not necessary; 5-Procedure might be necessary; 9-Procedure is clearly necessary.

	NORMAL OR LOW RISK			MODERATELY HIGH RISK			VERY HIGH RISK			
	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	
NO SYMPTOMS ON MAXIMAL MEDICAL THERAPY (NOT PREVIOUSLY RECEIVING MAXIMUM MEDICAL THERAPY)										
A1.LEFT MAIN DISEASE (PROTECTED LEFT MAIN)										
1. Ejection fraction >35%	1 1 1 2 4 1 2 3 4 5 6 7 8 9 (8.0, 1.4, A)									(379-387)
2. Ejection fraction 15-35%	1 1 1 2 4 1 2 3 4 5 6 7 8 9 (8.0, 1.7, A)									(388-396)
3. Ejection fraction <15%	1 2 1 1 3 1 1 2 3 4 5 6 7 8 9 (7.0, 1.8, I)									(397-405)
A2.LEFT MAIN DISEASE (UNPROTECTED LEFT MAIN)										
1. Ejection fraction >35%	1 2 6 1 2 3 4 5 6 7 8 9 (9.0, 0.4, A)			2 3 4 1 2 3 4 5 6 7 8 9 (8.0, 0.7, A)			1 2 2 1 3 1 2 3 4 5 6 7 8 9 (7.0, 1.2, I)			(406-414)
2. Ejection fraction 15-35%	1 2 6 1 2 3 4 5 6 7 8 9 (9.0, 0.4, A)			3 2 4 1 2 3 4 5 6 7 8 9 (8.0, 0.8, A)			1 3 1 1 3 1 2 3 4 5 6 7 8 9 (7.0, 1.3, I)			(415-423)
3. Ejection fraction <15%	1 1 2 3 2 1 2 3 4 5 6 7 8 9 (8.0, 1.0, A)			1 2 3 2 1 2 3 4 5 6 7 8 9 (7.0, 1.1, I)			1 5 1 1 1 2 3 4 5 6 7 8 9 (5.0, 1.0, A)			(424-432)
B. THREE VESSEL DISEASE										
1. Ejection fraction >35%	3 1 5 1 2 3 4 5 6 7 8 9 (8.0, 0.8, I)				3 2 2 2 1 2 3 4 5 6 7 8 9 (6.0, 1.0, I)					(433-441)
2. Ejection fraction 15-35%	3 2 4 1 2 3 4 5 6 7 8 9 (7.0, 0.8, I)				1 2 3 1 2 1 2 3 4 5 6 7 8 9 (6.0, 1.0, I)					(442-450)
3. Ejection fraction <15%	1 4 2 1 1 1 2 3 4 5 6 7 8 9 (5.0, 0.9, A)			2 3 3 1 1 2 3 4 5 6 7 8 9 (5.0, 0.9, A)						(451-459)

Necessity scale: 1=Procedure is clearly not necessary; 5=Procedure might be necessary; 9=Procedure is clearly necessary.

Chapter 2 CHRONIC ANGINA	NORMAL OR LOW RISK			MODERATELY HIGH RISK			VERY HIGH RISK			
	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	
C. TWO VESSEL DISEASE WITH PROXIMAL LEFT ANTERIOR DESCENDING INVOLVEMENT										
1. With a very positive exercise ECG										
a. Ejection fraction >35%		1 3 3 2 1 2 3 4 5 6 7 8 9 (7.0, 0.9, I)				1 1 4 2 1 1 2 3 4 5 6 7 8 9 (6.0, 0.8, I)			1 5 2 1 1 2 3 4 5 6 7 8 9 (5.0, 0.7, A)	(460-468)
b. Ejection fraction 15-35%		1 3 4 1 1 2 3 4 5 6 7 8 9 (7.0, 0.8, I)				1 1 5 1 1 1 2 3 4 5 6 7 8 9 (6.0, 0.7, A)			1 1 5 1 1 1 2 3 4 5 6 7 8 9 (5.0, 0.7, A)	(469-477)
c. Ejection fraction <15%	1 3 3 1 1 1 2 3 4 5 6 7 8 9 (5.0, 1.1, A)									(478-486)
2. With a moderately positive, indeterminate, or negative exercise ECG, or exercise ECG not done										
a. Ejection fraction >35%										(487-495)
b. Ejection fraction 15-35%										(496-504)
c. Ejection fraction <15%										(505-513)
D. TWO VESSEL DISEASE WITHOUT PROXIMAL LEFT ANTERIOR DESCENDING INVOLVEMENT										
1. With a very positive exercise ECG										
a. Ejection fraction >35%			1 1 5 2 1 2 3 4 5 6 7 8 9 (6.0, 0.6, A)			1 3 3 2 1 2 3 4 5 6 7 8 9 (6.0, 0.8, A)				(514-522)
b. Ejection fraction 15-35%			1 2 4 2 1 2 3 4 5 6 7 8 9 (6.0, 0.7, A)			3 4 2 1 2 3 4 5 6 7 8 9 (6.0, 0.9, A)				(523-531)
c. Ejection fraction <15%			1 3 1 2 1 1 2 3 4 5 6 7 8 9 (4.5, 1.1, A)							(532-540)
2. With a moderately positive, indeterminate, or negative exercise ECG, or exercise ECG not done										
a. Ejection fraction >35%			3 2 1 3 1 2 3 4 5 6 7 8 9 (4.0, 1.1, I)							(541-549)
b. Ejection fraction 15-35%										(550-558)

Necessity scale: 1-Procedure is clearly not necessary; 5-Procedure might be necessary; 9-Procedure is clearly necessary.

Chapter 2 UNSTABLE ANGINA	NORMAL OR LOW RISK			MODERATELY HIGH RISK			VERY HIGH RISK			
	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	
c. Ejection fraction <15%	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	(559-567)

Necessity scale: 1=Procedure is clearly not necessary; 5=Procedure might be necessary; 9=Procedure is clearly necessary.

Chapter 2 UNSTABLE ANGINA	NORMAL OR LOW RISK			MODERATELY HIGH RISK			VERY HIGH RISK			
	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	
E. SINGLE VESSEL DISEASE - PROXIMAL LEFT ANTERIOR DESCENDING										
1. With a very positive exercise ECG										
a. Ejection fraction >35%			1 1 1 3 3 1 2 3 4 5 6 7 8 9 (6.0, 1.3, I)			1 1 3 1 2 1 1 2 3 4 5 6 7 8 9 (5.0, 1.2, I)			2 3 3 1 1 2 3 4 5 6 7 8 9 (4.0, 1.2, I)	(568-576)
b. Ejection fraction 15-35%			1 4 1 3 1 2 3 4 5 6 7 8 9 (5.0, 1.3, I)			1 3 1 1 2 1 1 2 3 4 5 6 7 8 9 (5.0, 1.4, I)				(577-585)
c. Ejection fraction <15%			1 1 1 1 2 2 1 2 3 4 5 6 7 8 9 (5.5, 1.5, I)							(586-594)
2. With a moderately positive, indeterminate, or negative exercise ECG, or exercise ECG not done										
a. Ejection fraction >35%										(595-603)
b. Ejection fraction 15-35%										(604-612)
c. Ejection fraction <15%										(613-621)
F. SINGLE VESSEL DISEASE - ANY VESSEL OTHER THAN PLAD										
1. With a very positive exercise ECG										
a. Ejection fraction >35%			2 1 3 2 1 1 2 3 4 5 6 7 8 9 (6.0, 1.0, I)							(622-630)
b. Ejection fraction 15-35%			1 3 2 3 1 2 3 4 5 6 7 8 9 (6.0, 1.0, I)							(631-639)
c. Ejection fraction <15%										(640-648)
2. With a moderately positive, indeterminate, or negative exercise ECG, or exercise ECG not done										
a. Ejection fraction >35%										(649-657)
b. Ejection fraction 15-35%										(658-666)

Necessity scale: 1-Procedure is clearly not necessary; 5-Procedure might be necessary; 9-Procedure is clearly necessary.

	NORMAL OR LOW RISK			MODERATELY HIGH RISK			VERY HIGH RISK			
	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	Necessity of CABG	Necessity of INVASIVE	Necessity of PTCA	
c. Ejection fraction <15%	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	. . . . .	(667-675)

Necessity scale: 1=Procedure is clearly not necessary; 5=Procedure might be necessary; 9=Procedure is clearly necessary.

Appendix B

DATA ABSTRACTION FORM FOR CABG/PTCA STUDY

PART I: CARDIAC CATHETERIZATION

MCP: _____

ID #: _____ Hospital: _____

Date of Birth: _____ Age: _____ Sex: M____ F____

Date Entered on Waiting List for Cath: _____

Date of Cardiac Cath: _____

Angina Class at time of Cath: I II III IVA IVB IVC

Myocardial Infarct: Y___ N___ **Date of Last MI:** _____

Heart Failure Ever: Y___ N___ **Class of Heart Failure:** I II III IV
(If not documented, code as N)

Indication for Cath: ☐

1. Asymptomatic
2. Chest pain uncertain origin
3. Chronic stable angina
4. Unstable angina now
5. Unstable angina within past 3 months
6. Acute myocardial infarction
   a) non Q-wave
   b) Q-wave
7. Post infarction Angina
8. Near sudden death
9. Post CABG
10. Silent ischemia
11. Miscellaneous : Specify_____

Risk Factors for C.A.D.:	**Yes**	**No**	**No Data**
Diabetes Mellitus	☐	☐	☐
Hypertension	☐	☐	☐
Hyperlipidemia	☐	☐	☐
Smoker (within the last 2 years)	☐	☐	☐
Positive Family History	☐	☐	☐
High Risk Occupation:	☐	☐	☐

Drugs at time of Cath:	Yes	No	No Data
Long acting nitrates	☐	☐	☐
Beta blockers	☐	☐	☐
Calcium channel blockers	☐	☐	☐
IV Nitro	☐	☐	☐
IV Heparin	☐	☐	☐

Maximal Medical Therapy: ☐ ☐ ☐

Is there any contraindication
of the above 5 classes of drugs: ☐ ☐

Coronary Anatomy: [ ]

1. Protected (L) main
2. Unprotected (L) main
3. Three vessel disease
4. Two vessel disease with prox LAD
5. Two vessel without prox LAD
6. One vessel disease with prox LAD
7. One vessel disease other than LAD
8. No critical CAD

Ejection fraction: [ ]

1. >35%
2. 15-35%
3. <15% or severe systolic dysfunction

Exercise Stress Test: [ ]

1. Very Positive
2. Not very positive

Contraindication to CABG/PTCA: ☐Y ☐N

Appropriateness score for Cath: _____

Necessity Score for Cath: _____

IF INITIAL CAD PROCEED TO NEXT SECTION

PART II: CARDIOVASCULAR CONFERENCE

Date of cardiovascular conference: _____

	Yes	No	
Critical C.A.D.	☐	☐	
Clinical Contraindication for CABG	☐	☐	Describe:_____
Anatomic Contraindication for CABG	☐	☐	Describe:_____
Clinical Contraindication for PTCA	☐	☐	Describe:_____
Anatomic Contraindication for PTCA	☐	☐	Describe:_____

Indication for Revascularization: ☐

1. Chronic stable angina
2. Unstable angina
3. Acute myocardial infarction
   a) non Q-wave b) Q-wave
4. Post infarction angina
5. Asymptomatic
6. Near sudden death
7. Complications during PTCA
8. Revascularization with valve surgery

Operative Risk:

Female	+1
Weight > 1.5 ideal weight	+3
Wt: Ht: BMI:	
Diabetes mellitus	+3
Systolic BP > 140 mmHg	+3
Ejection fraction mild impairment	+2
Ejection fraction severe impairment	+4
Age 70-74	+7
75-79	+12
≥ 80	+20
First reoperation	+5
Second reoperation	+10
Preop intra-aortic balloon pump	+2
LV aneurysm	+5
Emergency surgery following cath on PTCA	+10
Dialysis dependent	+10
Catastropic state (acute structural defect, cardiogenic shock, ARF)	10-50
Rare problem (paraplegia, pacemaker, congenital HD, severe asthma)	2-10
Mitral valve surgery	+5
PA pressure ≥ 60	+8
Aortic valve surgery	+5
Aortic gradient > 120	+7
CABG at time of valve surgery	+2
COPD	+4
Claudication or amputation for PVD	+3
Symptomatic carotid artery disease	+4

Risk Score: ☐

Risk Group: ☐

1. Normal or low < 9
2. Moderately high 9-18
3. Very high > 18

Decision: ☐

1. Medical therapy
2. CABG
3. PTCA
4. PTCA with stent

High ischemic risk on noninvasive tests: Y ___ N ___ No data: _____

Date of cath: _____
Date entered on waiting list for CABG/PTCA: _____
Date procedure performed: _____

TO BE COMPLETED BY PHYSICIANS INVOLVED IN THE STUDY

Priority Score: ☐

Appropriateness Score:

CABG ☐ not candidate for PTCA

CABG ☐ is candidate for PTCA

PTCA ☐ compared to medical therapy

Necessity Score:

CABG ☐

Invasive ☐
(i.e., CABG/PTCA)

PTCA ☐

IF CABG/PTCA UNDERTAKEN PROCEED TO NEXT SECTION

PART III: Invasive Procedure CABG/PTCA

Procedure performed: ☐ Date Performed: _____

1. PTCA
2. PTCA + Stent
3. CABG

Indication for procedure: ☐

1. Asymptomatic
2. Chest Pain of Uncertain Origin
3. Chronic Stable Angina
4. Unstable angina
5. Unstable angina within the past 3 months
6. Acute Myocardial Infarction
7. Post Infarction Angina
8. Post-CABG
9. Miscellaneous:
   - (a) Near Sudden Death
   - (b) life threatening ventricular arrythmias
   - (c) unexplained cardiomegaly or CHF
   - (d) surgical candidate for valvular procedure
   - (e) surgical candidate for heart transplant
   - (f) congenital heart disease
   - (g) renal artery disease
   - (h) abdominal aortic aneurysm (asending)
   - (i) thoracic aortic aneurysm (descending)
   - (j) pre-op carotid endarterectomy
   - (k) pre-op peripheral vascular surgery
   - (l) suspected LV aneurysm

Complications of PTCA (within 24 hrs):	**Yes**	**No**
Failed to dilate	☐	☐
Emergency CABG	☐	☐
Cardiac arrest	☐	☐
Myocardial infarct	☐	☐
Stroke	☐	☐
Arrythmia requiring defib	☐	☐
Insertion of pacemaker	☐	☐
Death	☐	☐
Restenosis	☐	☐

Complications of CABG (during post-operative stay):	**Yes**	**No**	
Reoperation	☐	☐	
Vent Assistance > 3 days	☐	☐	
Cardiac arrest	☐	☐	
Myocardial infarct	☐	☐	
Sternal wound infection	☐	☐	
Groin/leg wound infection	☐	☐	
Mediastinitis	☐	☐	
Stroke	☐	☐	
Arrhythmia requiring defib	☐	☐	
Arrhythmia requiring pacemaker	☐	☐	
Acute renal failure requiring dialysis	☐	☐	
Death	☐	☐	
Other	☐	☐	Specify: _____

Date of Admission: _____ Date of Discharge: _____
Length of stay: _____

TO BE COMPLETED BY PHYSICIANS INVOLVED IN THE STUDY

Priority Score: ☐

Appropriateness Score: CABG ☐ not candidate for PTCA

CABG ☐ is candidate for PTCA

PTCA ☐ compared to medical therapy

Necessity Score: CABG ☐

Invasive (i.e., CABG/PTCA) ☐

PTCA ☐

Appendix C

DEFINITIONS USED BY PANEL IN FINAL RATINGS OF INDICATIONS

To use the indications and ratings, the terms used in the indications must be explicitly defined. What follows are the definitions agreed to by the panel prior to completing their final round of ratings.

1. RISK FACTORS

The following are six risk factors for coronary artery disease: diabetes mellitus, hypertension, hypercholesterolemia or other atherogenic dyslipidemia, smoking, positive family history (history of a myocardial infarction occurring in a grandparent, parent, sibling, aunt, or uncle at age less than 50 years), or male sex.

2. HIGH RISK OCCUPATION

A high risk occupation is one in which a patient developing sudden chest pain or sudden death while at work would endanger the lives of others (e.g., truck drivers, airplane pilots, bus drivers, and air traffic controllers).

3. MAXIMUM MEDICAL THERAPY

The patient has received drugs from at least two of the three major categories of anti-anginal medications (nitrates, calcium channel blockers, and beta-blockers); or has received one category of medication and has a contraindication (e.g., a patient with asthma may not be a candidate for beta-blockers) or intolerance to at least one of the other two categories of medications; or has a contraindication or intolerance to all three categories.

4. EXERCISE STRESS TEST RESULTS

a. **Very positive:** during the first 3 minutes of the test [or heart rate is less than 120 beats/minute (off beta-blockers) or less than 6.5 METS] the patient develops: (1) 1 mm or more of horizontal or downsloping ST segment depression that is present 80 msec after the J-point or (2) typical angina; or decrease in systolic blood pressure of 20 mm mercury or more; or more than 2 mm of

horizontal or downsloping ST depression at any time; or persistence of ST depression greater than 6 minutes postexercise.

b. **Positive:** after the first 3 minutes of the test the patient develops: (1) 1 mm or more of horizontal or downsloping ST segment depression that is present 80 msec after the J-point or (2) typical angina occurs.

c. **Indeterminate:** the absence of a very positive or positive test in a patient who fails to reach at least 85 percent of the predicted maximum heart rate or a heart rate–blood pressure product (heart rate × systolic arterial pressure ÷ 100) less than 250 without evidence of a positive test or the presence of conduction abnormalities (e.g., Wolff-Parkinson-White syndrome or left bundle branch block) that prevent the interpretation of ST segment changes during exercise.

d. **Negative:** the absence of a very positive, positive, or indeterminate test in a patient who achieves at least 85 percent of the predicted maximum heart rate or a heart rate–blood pressure product (heart rate × systolic arterial pressure ÷ 100) of 250 or greater.

5. STRESS IMAGING STUDY

We include a variety of tests in the category of stress imaging study: (1) Thallium scintigraphy (exercise or dipyridamole), (2) Echocardiography (exercise, dipyridamole, or dobutamine), (3) Radionuclide ventriculography (exercise, dipyridamole). These tests are categorized as: (1) very positive, (2) positive, (3) indeterminate, or (4) negative. Definitions for the results of each test are provided below.

a. Thallium Scintigraphy Results

1. **Very Positive:** a large anterior wall defect, or multiple defects (more than one arterial territory), or increased lung uptake of thallium in the absence of depressed left ventricular function at rest (ejection fraction < 35 percent).

2. **Positive:** reversible (partial or complete) thallium distribution in one arterial region during exercise.

3. **Indeterminate:** nonreversible (fixed) thallium distribution defect or abnormal distribution associated with increased lung uptake in the presence of depressed left ventricular function at rest (ejection fraction < 35 percent).

4. **Negative:** test does not meet the criteria for very positive, positive, or indeterminate.

b. Echocardiography Results

1. **Very positive:** multiple areas of dyskinesia or hypokinesia, or a large anterior area change, induced by exercise.

2. **Positive:** exercise-induced wall motion abnormality not present at rest or induced worsening of wall motion abnormality (e.g., patient has hypokinesia at rest and develops akinesia or dyskinesia) in one arterial region.

3. **Indeterminate:** resting wall motion abnormality or lack of a hyperkinetic response.

4. **Negative:** test does not meet the criteria for very positive, positive, or indeterminate.

c. Radionuclide Ventriculography Results

1. **Very positive:** a fall in left ventricular ejection fraction of greater than 15 percentage points during exercise or multiple exercise-induced areas of hypokinesia or akinesia.

2. **Positive:** a fall in left ventricular ejection fraction of 5 to 15 percentage points during exercise or left ventricular ejection fraction is less than 50 percent during exercise or exercise-induced wall motion abnormality not present at rest or exercise-induced worsening of a wall motion abnormality (e.g., a patient has hypokinesia at rest and develops akinesia or dyskinesia).

3. **Indeterminate:** resting wall motion abnormality or an increase in left ventricular ejection fraction by less than 5 percentage points or decrease in left ventricular function by less than 5 percentage points or resting ejection fraction less than 50 percent.

4. **Negative:** test does not meet the criteria for very positive, positive, or indeterminate.

6. ASYMPTOMATIC

Patients with no prior history of ischemic heart disease (e.g., no history of angina or myocardial infarction).

7. SILENT ISCHEMIA

Electrocardiographic evidence of ischemia may be detected by three methods: (1) the standard 12-lead electrocardiogram, (2) an exercise stress test, or (3) ambulatory (Holter) electrocardiography. For our definition, we refer only to silent ischemia detected by ambulatory (Holter) electrocardiography.

a. Significant silent ischemia: at least 1 mm of downsloping or horizontal ST depression that is: (1) one or more episodes lasting longer than 5 minutes, or

(2) two or more episodes lasting 1 or more minutes each, separated by 1 minute or more, when the cumulative total of episodes is greater than 5 minutes.

b. Trivial/no silent ischemia: does not meet the criteria for significant silent ischemia.

8. MET

A MET unit is equal to an oxygen uptake of 2.5 ml oxygen per kilogram body weight per minute at rest. Many exercise tests are standardized in terms of oxygen consumption (i.e., 2 METS = twice the oxygen consumption at rest).

9. CONTRAINDICATIONS TO CORONARY ARTERY BYPASS GRAFT SURGERY/PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

In patients with other serious illnesses, such as those illustrated here, we generally assume they would not be presenting for coronary angiography.

a. Terminal illness, such as cancer, AIDS, severe COPD [chronic obstructive pulmonary disease], hepatic failure, where a reasonable prognosis is six months or less.

b. Advanced dementia.

c. Severe impairment in ability to perform the basic activities of daily living (i.e., a score of 3/6 or less using the Katz Activities of Daily Living criteria) because of noncardiac disease.

10. ANGINA

Angina is present if any three of the following four conditions are met: (1) substernal or left-sided chest pain; (2) radiation of the pain to the left arm, left neck, or left jaw; (3) the pain is usually precipitated by exercise; and (4) the pain is relieved within 10 minutes by rest or sublingual nitroglycerin. Angina class definitions follow:

a. Angina on mild exertion: includes patients in the Canadian Cardiovascular Society Classes III and IV:

   i. Class III = angina on walking one or two level blocks.

   ii. Class IV = angina on any physical activity, including angina at rest.

b. Angina on moderate exertion: includes patients in the Canadian Cardiovascular Society Classes I and II:

   i. Class I = angina on strenuous exertion.

ii. Class II = angina on walking or climbing stairs rapidly or in cold or in wind or under emotional stress.

11. CHEST PAIN OF UNCERTAIN ORIGIN (ATYPICAL ANGINA)

The patient has chest pain and two or fewer of the conditions described for angina.

12. UNSTABLE ANGINA

a. In patients with previously stable angina, the angina increases in intensity, duration, or frequency or occurs at rest (prolonged duration, not fleeting pain).

b. In patients without previous history of angina, the initial episode occurs at rest or if it occurs with exertion it is unrelieved by rest ("acute coronary insufficiency").

13. CONGESTIVE HEART FAILURE

Heart failure diagnosed clinically that is persisting, is associated with a decrease in functional status, and requires ongoing medical treatment.

Definitions:

Coronary artery disease: reduction in luminal diameter of L main coronary artery of 50% or greater by visual inspection, or reduction in luminal diameter of one major coronary artery of 70% or greater by visual inspection.

Unstable angina: Chest pain thought to be due to myocardial ischemia, requiring hospitalization because of difficulty in control or concern about the possiblity of myocardial infarction. This includes: (1) recent increase in the intensity, frequency, or duration of chronic angina; (2) the development of angina at rest; or (3) new onset of severe chest pain ("acute coronary insufficiency"). Revascularization is carried out while the patient is in the hospital or within 4 weeks of admission for unstable angina.

Angina Class
- I: angina on strenuous exertion
- II: angina on walking or climbing stairs rapidly
- III: angina on walking one or two level blocks
- IVa: unstable angina, pain resolved with intensified medical therapy now stable on oral medication
- IVb: unstable angina on oral therapy, symptoms improved but angina with minimal provocation
- IVc. symptoms not manageable on oral therapy, requires coronary care or parenteral medication, may be hemodynamically unstable.

Significant coronary artery disease:

a. Left main disease: reduction in the luminal diameter of the left main coronary artery of 50 percent or greater by visual inspection or formal calibration of angiographic findings. Protected left main is defined by presence of a patent bypass graft to the LAD (left anterior descending) or circumflex arteries or by collateral flows to these arteries form a patent RCA (right coronary artery).

b. Three-vessel disease: reduction in the luminal diameter of all three major coronary arteries of 50 percent or greater by visual inspection or calibration of angiographic findings. If measured by visual inspection, at least one vessel must have 80 percent stenosis. The panel believed that these represented equivalent assessments of the extent of the disease.

c. Two-vessel disease: reduction in the luminal diameter of two major coronary arteries of 50 percent or greater by visual inspection or calibration of angiographic findings. If measured by visual inspection, at least one vessel must have 70 percent stenosis.

d. One-vessel disease: reduction in the luminal diameter of one major coronary artery (not left main)of 70 percent or greater by visual inspection or 50 percent by calibration.

e. Proximal left anterior descending (PLAD): Viability of a major amount of the anterior wall of the left ventricle is in jeopardy owing to reduction in luminal diameter of PLAD by 70 percent or greater by visual inspection or 50 percent by quantitative analyses. (For purposes of chart abstraction and formal utilization analysis, the definition can be narrowed to PLAD involvement that is proximal to the first septal perforator).

Very positive Exercise ECG: Positive Stage I Bruce protocol: (1) During the first 3 minutes of the test (or onset at heart rate less than 120 beats/minute off beta-blockers, or less than 6.5 METS) the patient develops: (a) 1 mm or more of horizontal or downsloping ST segment depression that is present 80 msec after the J-point or (b) the occurrence of typical angina; or (2) a decrease in systolic blood pressure of 20 mm mercury or more; or (3) more than 2 mm of horizontal or downsloping ST depression at any time; or (4) persistence of ST depression for greater than 6 minutes post-exercise.

Operative Risk Score

Female	+1
Weight > 1.5 ideal weight	+3
Diabetes mellitus	+3
Systolic BP > 140 mmHg	+3
Ejection fraction mild impairment	+2
Ejection fraction severe impairment	+4
Age 70-74	+7
75-79	+12
≥ 80	+20
First reoperation	+5
Second reoperation	+10
Preop intra aortic balloon pump	+2
LV aneurysm	+5
Emergency surgery following CA or PTCA	+10
Dialysis dependent	+10
Catastrophic state	10-50
Rare problem	2-10
Mitral valve surgery	+5
PA pressure ≥ 60	+8
Aortic valve surgery	+5
Aortic gradient > 120	+7
CABG at time of valve surgery	+2
Chronic obstructive lung disease	+4
Peripheral vascular disease with claudication or amputation	+3
Symptomatic carotid artery disease	+4

Maximum Medical Therapy

a. **Chronic stable angina:** The patient has received drugs from at least two of the three major categories (nitrates, beta-blockers, and calcium antagonists) or the patient has received one class of medication, but there is a note in the chart that the patient is unable to tolerate the others.

b. **Unstable angina:** Must meet one of the following criteria:

1. The patient has received drugs from at least two of the following major classes of drugs: nitrates, beta-blockers, calcium channel antagonists, and intravenous heparin (except TKO Hep-lock), or

2. Receiving intravenous nitroglycerin, or

3. Receiving one class of drugs in (a) above, with a note in the record that indicates the patient is unable to tolerate other drugs.

Contraindications to CABG

a. Terminal illness, such as cancer, AIDS, severe COPD, hepatic failure, where a reasonable prognosis is six months or less.

b. Advanced dementia.

c. Severe impairment in ability to perform basic activities of daily living (Katz score of 3/6 or below) because of noncardiac disease.

Medication List (Q72)

Group 1= Nitrates
Group 2= Beta blockers
Group 3= Calcium channel blockers
Group 4= IV NTG
Group 5= IV heparin

Grp	Medication
2	Acebutolol
3	Adalat
3	Adalat FT
3	Adalat PA
1	Angijen Green
3	Apo-diltiaz
1	Apo-ISDN
2	Apo-metoprolol
2	Apo-nadol
3	Apo-nifed
2	Apo-pindol
2	Apo-propanolol
2	Apo-timol
3	Apo-verap
1	Arcotrate
2	Atenolol
1	Baritrate
2	Betaloc
2	Betaxalol
2	Betim
2	Blocadren
3	Calan
3	Calan SR
5	Calcilean
5	Calciparine
1	Cardabid
3	Cardene
1	Cardilate
3	Cardizem
3	Cardizem SR
2	Carteolol
1	Cartrax
2	Cartrol
1	Cedocard-SR
1	Coradur
2	Corgard
1	Cordbid

Grp	Medication
1	Corovax Tymcaps
2	Corzide
1	Deponit NTG Film
1	Desatrate
2	Detensol
1	Dilar
1	Dilatrate-SR
3	Diltiazem
1	Duotrate
1	Erythri-tyltetranitrate
1	Glyceryltrinitrate
1	Gly-trate
5	Hepalean
5	Heparin Leo
5	Heparin sodium (IV)
2	Inderal
2	Inderal LA
2	Inderide
2	Inderide LA
2	Ipran
1	ISDN
1	ISMN
1	Iso-Bid
1	Iso-D
1	Isonate
3	Isoptin
3	Isoptin SR
1	Isordil
1	Isosorb
1	Isorsorbide-dinitrate
1	Isosorbide-mononitrate
1	Isotrate
2	Kordanor

Grp	Medication
2	Labetolol
2	Levatol
5	Liquaemin sodium (IV)
2	Lopressor
1	Maso-Trol
2	Metoprolol
1	Mitrate
1	Minitran
2	Nadolol
3	Nicardipene
3	Nifedipine
1	Niong
1	Nitrate
1	Nitrin
1	Nitro
4	Nitro (IV)
1	Nitro-Bid
4	Nitro-Bid (IV)
1	Nitro-Cap TD
1	Nitrocels
1	Nitrocine TD
1	Nitrocine Timecaps
1	Nitro-Dial
1	Nitrodisc
1	Nitro-Dur
1	Nitrogard
1	Nitrogard-SR
1	Nitroglycerin
4	Nitroglycerin (IV)
1	Nitroglyn
4	Nitroject
1	Nitrol
1	Nitrolin
1	Nitro-Lyn
1	Nitromist

Grp	Medication
1	Nitro-paste
1	Nitro-patch
1	Nitrospan
1	Nitrostabilin
1	Nitrostat
4	Nitrostat (IV)
1	Nitro-TD
2	Normodyne
2	Normozide
2	Novo-metoprolol
3	Novo-nifedin
2	Novo-pranol
1	Novo-sorbide
3	Novo-veramil
1	NT
4	NT (IV)
1	NTG
4	NTG (IV)
1	NTP
1	NTS
4	NTS (IV)
1	Nyglycon
2	Oxprenolol
2	Penbutolol
1	Pent-T-80
1	Penta-Cap
1	Penta-E
1	Penta-ESA
1	Pentaerythritoltet-ranitrate
1	Pentaforte-T
1	Penta-Tal
1	Pentrate TD
1	Pentritol
1	Pentylan
1	Periospan
1	Perlinganit

Grp	Medication
1	Petro
2	Pindolol
3	Procardia
3	Procardia XL
2	Propranolol
1	P-T-T
1	Quintrate
1	Rate
2	Sectral
1	Sorate
1	Sorbid SA
1	Sorbide
1	Sorbitrate
2	Syn-nadolol
2	Syn-pindolol
2	Tenoretic
2	Tenormin
3	Tilazem
2	Timacor
2	Timolide
2	Timolol
2	Trandate
1	Transdermal NTG
1	Transderm Nitro
2	Trasicor
1	Trates
4	Tridil (IV)
1	Vasolate
3	Verapamil
3	Verapamil SR
3	Verelan
2	Visken

L01

Appendix D

A Method of Uniform Stratification of Risk for Evaluating the Results of Surgery in Acquired Adult Heart Disease

Victor Parsonnet, MD, FACC, David Dean, and Alan D. Bernstein, EngScD, FACC

The purpose of the study was to devise a method of stratifying open-heart operations into levels of predicted operative mortality, using objective data that are readily available in any hospital. Following univariate regression analysis of 3,500 consecutive operations, 14 risk factors were chosen that met these conditions. A few factors were excluded because they were insufficiently objective or not always available. An additive model was constructed, using the factors chosen, to calculate the probability of mortality within 30 days. The method was then tested prospectively in 1,332 open-heart procedures at the Newark Beth Israel Medical Center. Patients were categorized in five groups of increasing risk: good (0–4%), fair (5–9%), poor (10–14%), high (15–19%), and extremely high (≥20%). The correlation coefficient of anticipated and observed operative mortality, using the additive model, was 0.99. The operative mortality also correlated closely with complication rates and length of hospital stay. The additive model was compared with a second model based on logistic multiple regression; the resulting correlation coefficient was 0.85. The method was also tested at two other hospitals; although their sample sizes were smaller, the outcomes in each risk group were comparable with those at this institution. The collection of data proved to be acceptably simple for all three centers. This study demonstrates that it is possible to design a simple method of risk stratification of open-heart surgery patients that makes it feasible to analyze operative results by risk groups and to compare results in similar groups between institutions. Wider application of the system is recommended. (*Circulation* 1989;79(suppl I):I-3–I-12)

Those who pay for health care, such as Medicare and insurance carriers, have a well-founded interest in the results of surgical procedures. The cost of surgery is influenced by the duration of hospitalization, the severity of illness, and the complexity and intensity of care. For this reason, the results of open-heart surgery in the Medicare population were made public in 1986 and 1987.[1] Listed by region and by hospital, such data are also useful in clinical research to assess the prevalence of cardiovascular disease, the effectiveness of therapy, and trends in medical practice.

An inherent difficulty in comparing the results of surgery of one institution (or individual) with those of another is the lack of a simple and widely accepted quantification of risk—one that defines the severity of disease and identifies the many variables that contribute to a predictable outcome. The Health Care Finance Administration, for example, can relate the results of surgery to age, sex, race (white and nonwhite), and certain comorbidities, but not to the severity of disease, because it receives all its data from Medicare billing which, in turn, is usually based on the facesheet of the hospital chart, an unreliable source of information.[2]

Physicians and hospitals often consider high mortality figures among their patients to be misleading because they believe that their patients are in a higher-risk category than others. There has been no way to resolve this issue without a chart-by-chart review, obviously an impossible task.

Risk-stratification methods have been devised in the past. Although some have been accurately predictive of operative mortality, they are generally too complicated for practical use, often requiring detailed data that may be unavailable. Scores quantifying the degree of ventricular dysfunction or the extent of coronary arteriosclerosis have been useful when resources and personnel are available to collect and process such data, but they are too complex and costly for universal application. (This

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TABLE 2. Components of the additive model.

Risk factor	Assigned weight
Female gender	1
Morbid obesity (≥1.5×ideal weight)	3
Diabetes (unspecified type)	3
Hypertension (systolic BP>140 mm Hg)	3
Ejection fraction (%): _____ (actual value when available)	
Good (≥50)	0
Fair (30–49)	2
Poor (<30)	4
Age (yr): _____	
70–74	7
75–79	12
≥80	20
Reoperation	
First	5
Second	10
Preoperative IABP	2
Left ventricular aneurysm	5
Emergency surgery following PTCA or catheterization complications	10
Dialysis dependency (PD or Hemo)	10
Catastrophic states (e.g., acute structural defect, cardiogenic shock, acute renal failure)*	10–50†
Other rare circumstances (e.g., paraplegia, pacemaker dependency, congenital HD in adult, severe asthma)*	2–10†
Valve surgery	
Mitral	5
P.A pressure≥60 mm Hg	8
Aortic	5
Pressure gradient >120 mm Hg	8
CABG at the time of valve surgery	2

BP, blood pressure; IABP, intra-aortic balloon pump; PTCA, percutaneous transluminal coronary angioplasty; PD, peritoneal dialysis; Hemo, hemodialysis; HD, heart disease; PA, pulmonary artery; CABG, coronary artery bypass graft.

*On the actual worksheet, these risk factors require justification.

†Values were predictive of increased risk of operative mortality in univariate analysis.

Results

Of 17 variables (Table 1) subjected to univariate analysis, 15 fulfilled the purposes of the study (Table 2). The distribution of patients by risk is shown in Figure 1. The mean predicted operative mortality was 10.4%. The mean observed operative mortality was 8.9%. Figure 2 depicts a comparison between predicted and actual outcomes for each of the five risk ranges. Regression analysis revealed a correlation coefficient of 0.99 (Figure 3). This figure was obtained by comparing the mean predicted operative mortality for all patients in each of the five intervals with the observed proportion of patients who actually died within the interval. A comparison of the

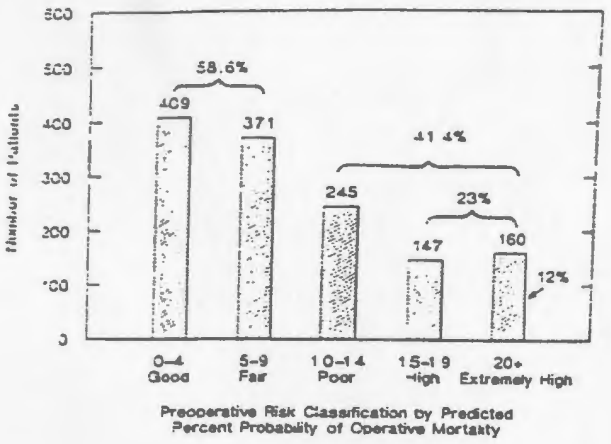

FIGURE 1. *Bar graph of the distribution by preoperative risk classification of 1,332 patients included in the study at the Newark Beth Israel Medical Center.*

univariate and multivariate models showed a correlation coefficient of 0.85 (Figure 4).

To test the assumption that any kind of heart surgery might fit the predictive score, three general types of operations were compared: aortocoronary bypass alone, valves alone, and valves plus aortocoronary bypass (Figure 5). The operative mortality in each subgroup resembled the results of the groups combined. The differences were not statistically significant. A comparison of the overall results obtained at this institution with those from the two other centers testing this method is shown in Figure 6, and Figure 7 shows a comparison of the results observed at the three centers taken as a unit, with the mortality rates predicted by the additive model.

Further analyses were performed, comparing the complications in various risk groups. Figure 8 illustrates that the incidence of nonfatal complications is

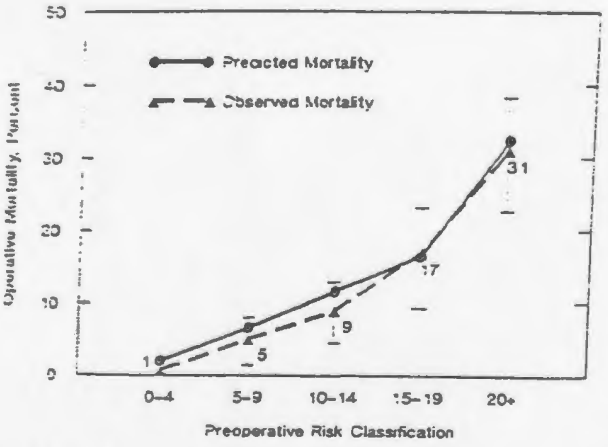

FIGURE 2. *Graph of a comparison of predicted and observed outcomes of surgery for 1,332 consecutive procedures, shown as a function of preoperative risk classification. Narrow vertical bars depict the 95% confidence limits for each observed value. (The score is the predicted mortality rate.) Numbers by the triangles indicate actual mortality in the observed groups.*

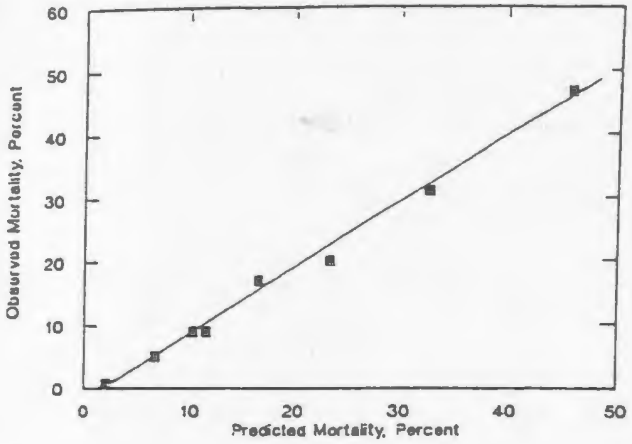

FIGURE 3. *Graph of the results of a linear regression comparison of predicted and observed mortality rates for 1,332 consecutive open-heart procedures. The correlation coefficient was 0.99. (In this graph, the entire cohort was divided into slightly smaller groups to provide more data points.)*

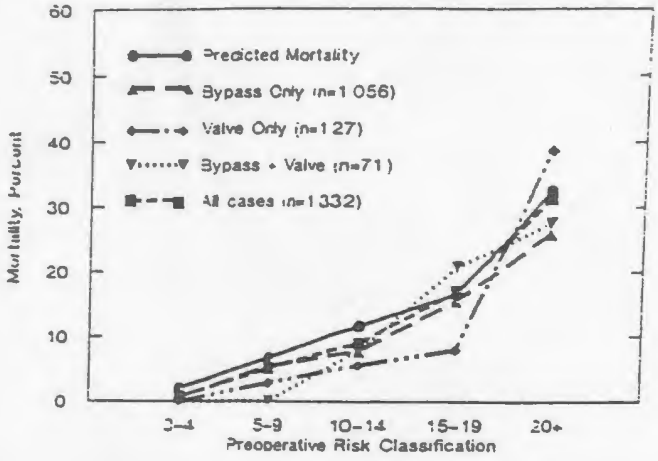

FIGURE 5. *Graph of a comparison of the overall predicted mortality rates with outcomes observed in three subcategories of surgery and with all subcategories taken together, preoperative risk classification. Data from Figure 2 are included for comparison. (Differences among observed subcategory mortality rates and differences from the predicted mortality rates were not statistically significant.*

distinctly related to the severity of disease. (Any and all postoperative problems were counted as complications, including such relatively common and benign problems as atrial fibrillation, hypokalemia-related arrhythmias, and stitch infections. Deaths were excluded from the tabulations.) A similar correlation was found with the duration of hospitalization (Figure 9).

Discussion

Risk Factors Included

Several factors known to be related to operative mortality, such as New York Heart Association classification and chronic obstructive pulmonary disease, were excluded (see below) because they are subject to observer bias. Left-ventricular ejection fraction, admittedly of immense predictive value, was not measured in every patient; therefore, an estimate was acceptable. In general, it was desired to limit the number of criteria so the collection of data would not become burdensome. The selected risk factors are discussed below, and the assigned scores are shown in Table 2.

Gender. While there has been considerable difference of opinion regarding the importance of gender as a predictive variable, it is the consensus that females have a higher operative mortality than males, perhaps because of smaller artery size. Whatever the cause, females tend to fare less well than males.[11-16,25,30-32]

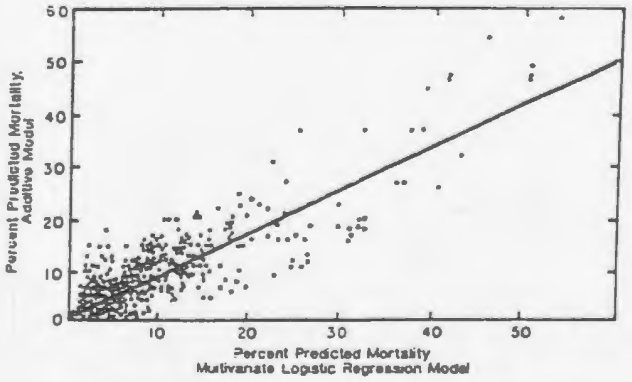

FIGURE 4. *Scatter plot of the results of a linear regression comparison of predicted mortalities obtained with the additive and multivariate logistic regression models. The correlation coefficient was 0.85. A regression line is superimposed.*

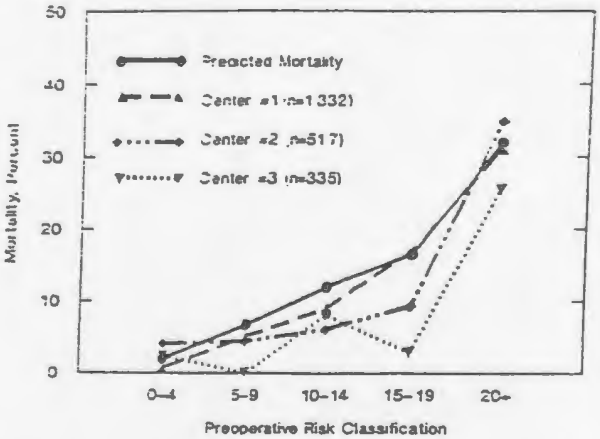

FIGURE 6. *Graph of a comparison of predicted and observed outcomes of surgery at three centers participating in the prospective evaluation of the additive model (see text for details). Differences among observed subcategory mortality rates and differences from predicted mortality rates were not statistically significant.*

Preoperative intra-aortic balloon counterpulsation. When an intra-aortic balloon is in place at the time of surgery, indications for its use already are evident from other independent factors. Nevertheless, it is hard to discount the occasional disastrous result of irreversible ischemia of a lower limb, which at times contributes to a patient's demise. Others also have found it to be an independent risk factor.[14,16]

Morbid obesity. For the purpose of this study, morbid obesity was defined as at least 1.5 times normal weight. The impact of obesity on operative mortality after any major operation is well known: this was confirmed by logistic regression analysis of the present series. Those responsible for the collection of data were provided with a table of normal and 1.5×normal weights.[71]

Mitral valve surgery. After considering the many variables that can affect mortality in valve operations, it was concluded that, in the context of this study, only the pulmonary artery systolic pressure was of critical importance in differentiating between low- and high-risk situations. A level of 60 mm Hg was chosen as the value that differentiated mild from severe pulmonary hypertension. This value is consistent with those reported in the literature.[11,20,27,72-75]

Aortic valve surgery. A pressure difference of 120 mm Hg across the aortic valve was selected as the value differentiating mild from severe stenosis. The risk inherent in aortic insufficiency also may be reflected in ventricular dysfunction and, therefore, in the ejection fraction. The prediction of operative mortality is complex, because it depends not only on the degree of valvular stenosis or regurgitation but on its chronicity, on the degree of left-ventricular hypertrophy, and on the presence of congestive heart failure. The value selected was obtained from univariate analysis of the results of isolated aortic-valve replacement and from a review of the pertinent recent literature.[27,67,74,76,77]

Combined valve replacement and coronary artery bypass. If two valves were operated on, the 2 values were added. If concomitant aortocoronary bypasses were performed, 2 more points were added. For three valves (rarely seen in this series) or for tricuspid or pulmonary valve surgery, the surgeon was asked to estimate the surgical risk. In reviewing the literature, it is difficult to arrive at a consensus on the risk of adding bypass grafting to valve replacement. The analysis of this series showed a small additive effect, as have other analyses.[11,42,72,77,78] Some workers, however, have found little or no difference in operative mortality.[27,74]

Failed angioplasty or acute cardiac catheterization emergency. In an earlier study of 67 operations for acute angioplasty failures at this institution, there was an 11% operative mortality rate, similar to some rates reported in the available literature.[79] There was little information on the outcome of similar emergencies after cardiac catheterization, but the clinical features are so similar that the outcome of emergency aortocoronary bypass surgery is assumed to be the same.

Reoperations. The present analysis showed that reoperation represents a distinct and important factor in predicting operative mortality. Although there is some difference of opinion on this issue in the literature, with some authors reporting no impact of reoperation,[74,76] most reports tend to support this evaluation.[13,25,29,41,48,64,73]

Catastrophic states. A catastrophic state was defined as major acute structural damage to the heart such as an acute ventricular septal defect or acute mitral valve regurgitation. In such instances, an estimate of risk was made by the surgical resident, and a space was provided on the data collection worksheet to permit justification of the value chosen.

An effort was made to avoid bias by limiting the need for the surgeon or his associates to assign a value. In this instance, however, it made little difference in the scoring outcome, because the need for such estimation usually was associated with coincidental independent risk factors that already had rendered the final composite score extremely high. Also, these procedures were so few that they had little effect on the calculation of individual weights used in the additive model.

Other rare circumstances. Other rare risk factors (Table 2) certainly play a role in the outcome of the surgery. In these situations, as well as in the previous category, the surgical resident was asked to provide an appropriate value.

Risk Factors Excluded

Certain factors known or suspected to affect mortality were omitted from the scoring system. Because a precondition of the study was the identification of criteria that were easily quantified and readily available, some factors known to represent important risks had to be omitted. Chronic obstructive pulmonary disease, for example, which is clearly an important element in survival, is almost indefinable unless detailed pulmonary function studies are performed.[12,80] The pulmonologist could not select a single quantitative clinical feature that would be of use in comparing one patient with another. Furthermore, for obvious logistic and practical reasons, many patients never receive a specific preoperative pulmonary workup.

Some factors were excluded as too subjective, or were available only after an operation, or were indefinable, or were not universally available. These include the number of bypasses, the use of the internal mammary artery, the presence and degree of mainstem stenosis, left ventricular end-diastolic pressure, extracranial cerebrovascular disease, cardiopulmonary bypass time, and operative priority.

The distribution of atherosclerotic lesions throughout the coronary tree is also a troublesome factor to the surgeon who must decide operability. In this particular matter there is great interobserver vari-

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KEY WORDS • risk assessment • open-heart surgery • mortality rate

Appendix E

CLINICAL PRACTICE

Assessment of priority for coronary revascularisation procedures

C. DAVID NAYLOR RONALD S. BAIGRIE BERNARD S. GOLDMAN
ANTONI BASINSKI

REVASCULARISATION PANEL AND CONSENSUS METHODS GROUP

To develop guidelines for ranking the urgency with which patients with angiographically proven coronary disease need revascularisation procedures, factors that a panel of cardiac specialists agreed were likely to affect urgency were incorporated into 438 fictitious case-histories. Each panelist then rated the cases on a 7-point scale based on maximum acceptable waiting time for surgery; 1 on the scale represented emergency surgery and 7 delays of up to 6 months. For only 1% of cases was there agreement on a single rating by at least 12/16 panelists. Results of this ranking exercise were used by the panel to draw up triage guidelines. The three main urgency determinants were (1) severity and stability of symptoms of angina (2) coronary anatomy from angiographic studies, and (3) results of non-invasive tests for risk of ischaemia. Together these three factors generally gave an urgency rating for any given case to within less than 0·25 scale points of the value predicted with all factors. A numerical scoring system was derived to permit rapid estimation of the panel's recommended ratings.

Lancet 1990; 335: 1070–73.

Introduction

Limited medical facilities and manpower often mean that patients with coronary heart disease (CHD) have to wait for revascularisation procedures. Informal criteria are therefore used by doctors to identify patients who deserve priority for treatment because of severity of symptoms or likelihood of early ischaemic events—a sorting process sometimes termed triage. In Ontario (population 9·5 million), the waiting times of several months for coronary artery bypass surgery (CABS) in some provincial hospitals and institutional variations in assignment of surgical priorities[1] led to the setting up of a panel of 11 cardiologists and 5 cardiac surgeons to develop criteria for allocating priority to patients. This report summarises the panel's consensus methods and recommendations, and sets out a simple scoring system to assess patients' priorities for surgery.

Methods

Consensus methods

The consensus process[2] was adapted from those used by researchers with the RAND Corporation[3-5] and the Canadian National Consensus Conference on Aspects of Cesarean Birth.[6,7] Factors that panelists agreed might be important in determining urgency of need for revascularisation were taken into account to create 438 case-histories. Most of these cases were suitable for CABS rather than for percutaneous transluminal coronary angioplasty (PTCA). An urgency rating scale, based on maximum reasonable delay before revascularisation, was adopted (table I). Two appropriateness nodes were added to the scale for panelists to indicate cases for which they thought revascularisation seemed questionable or contraindicated (table I); no urgency ratings were given if one or these nodes was chosen.

Each panelist was provided with a review (see below) on the potential risks of delayed surgery, and then asked to independently rank the 438 cases in questionnaire form. The maximum acceptable waiting period was to be measured from the time that results of angiographic investigation of anginal symptoms (table II) became available.

Panelists' answers were analysed, and each panelist received an anonymous report showing his ratings in relation to those of the others. Major patterns of disagreement were addressed and resolved at a second panel meeting, where consensus principles for triage were unanimously adopted.

Review of published work

The review (copies from C. D. N. on request) drew on all published randomised trials of medical versus surgical therapy for stable and unstable angina, and on some observational data from registry reports to appraise subgroups not included in trials. In contrast to other reviews delineating appropriateness of surgery,[8,9] the analysis dealt specifically with urgency. For example, if a trial showed that surgery did not start to confer a survival advantage over medical therapy until 12 months after randomisation, then medical therapy for the type of patient in the trial was judged to be safe for several months. This judgment entails an assumption that there is

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Level		Timing
1	Emergency	Immediate revascularisation
2	Extremely urgent	Within 24 hours
3	Urgent	24–72 hours
4	Semi-urgent	72 hours to 14 days same admission
5	Short list	2 weeks to 6 weeks
6	Delayed	6 weeks to 3 months
7	Marked delay	3 months to 6 months
	Questionable	whether revascularisation should be undertaken
	Inappropriate	for revascularisation to be undertaken.

Each urgency rating level represents the period within which the revascularisation procedure is expected to be done the outer time limit for each level represents the maximum acceptable waiting period for patients assigned that urgency rating

no latency of effect size—ie, that the benefit of surgery after a delay of several months would be the same as that of surgery at the outset. Mortality was the sole outcome analysed in the review; panelists were asked to use their own judgment as to symptom burden and risk of other morbid events.

Statistical methods

The incomplete factorial design of the questionnaire allowed use of least-squares regression to determine the weights for various factors within each of the five angina classes. Panelist ratings of "questionable" and "inappropriate" were excluded, and only urgency ratings were considered. Factors seen not to be important urgency determinants were then assessed for impact as appropriateness determinants. This entailed an analysis of how often changes in a given factor led to changes in panelist's ratings from urgent (grades 1–7) to "questionable" or "inappropriate".

A scoring system was also derived from the regression model. To reduce outlier influences, the highest and lowest one-eighth of responses were trimmed, and the trimmed mean ratings were analysed. Regression coefficients for the major urgency determinants were then combined to produce a score that quantitatively summarised the consensus principles adopted by the panel.

Results

Interpractitioner disagreement

For only 1% of cases was there agreement by at least 12/16 panelists on the ratings. However, when the scale was divided into three broad clinical categories (revascularise promptly, levels 1–4; place on a waiting list, levels 5–7; and no triage [questionable or inappropriate]), agreement by at least 12/16 panelists was reached for 60% of cases. Patterns of disagreement are explored elsewhere.[2]

TABLE II—MAJOR FACTORS AFFECTING URGENCY RANKING

A Presenting pain syndrome and therapeutic response

1. Stable angina on reasonable medical therapy: mild to moderate (Canadian Cardiovascular Society classes I–II).
2. Stable angina on reasonable medical therapy: severe (Canadian Cardiovascular Society class III).
3. Unstable angina, pain resolved with intensified medical therapy, and now stable on oral medication (panel class IV–A).
4. Unstable angina, on oral therapy, symptoms improved but angina with minimal provocation (panel class IV–B).
5. Symptoms not manageable on oral therapy, requires coronary care monitoring and parenteral medication, may be haemodynamically unstable (panel class IV–C).

B Coronary artery disease defined by angiography prototypical patterns below or equivalents*

1. Left mainstem stenosis with or without stenoses of other vessels.
2. Two-vessel or three-vessel disease, including proximal left anterior descending (LAD).
3. Three-vessel disease without significant involvement of the proximal LAD.
4. Single-vessel disease involving the proximal LAD.
5. Single-vessel or two-vessel disease without a proximal lesion of LAD.

C Reversible ischaemia on non-invasive tests

1. High risk: see text for definitions.
2. Not high risk: any test not meeting high risk criteria.

*"Equivalents" anatomical patterns not falling within the five prototypes are rated according to the closest equivalent in terms of viable myocardium at ischaemic risk.

Anatomical equivalent	Stable angina I–II	Stable angina III	Unstable angina IV–A	Unstable angina IV–B	Unstable angina IV–C
Left mainstem stenosis	5·40	4·85	4·75	3·40	2·15
Multivessel, including proximal LAD stenosis	6·15	6·00	5·50	3·90	2·55
Three-vessel, without proximal LAD stenosis	6·45	6·35	5·80	3·90	2·65
Single-vessel proximal LAD stenosis	6·80	6·55	5·80	4·05	2·90
One or two-vessel disease, no proximal LAD stenosis	6·95	6·65	6·15	4·15	3·05
Number to be subtracted if non-invasive tests suggest high ischaemic risk	0·90	0·75	0·75	n a	n a
Standard error of combined score (maximum.	0·11	0·06	0·08	0·03	0·03
Typical residual (mean squared error)	0·24	0·13	0·15	0·10	0·12
Maximum residual (predicted score vs trimmed mean rating)	0·45	0·32	0·45	0·28	0·28

All scores rounded to the nearest 0·05 for ease of reference, indices of precision and fit rounded to two decimal places
n/a = not applicable.

Major factors in urgency rankings

The three key determinants of urgency ranking were: (i) symptom status and response to medical therapy; (ii) coronary anatomy; and (iii) results of non-invasive tests for ischaemic risk (NIVTs).

Stable angina symptoms were defined according to the Canadian Cardiovascular Society classes I–III.[10] All cases with stable angina were presumed to be on standard medical therapy with tolerable side-effects. For unstable angina, the panel defined three subgroups of increasing severity ordered according to the response of symptoms to medical therapy (panel classes IV–A,B,C; table II); these should be pertinent to triage practices anywhere.

Five anatomical patterns of coronary disease were defined (table III). A 50% reduction in luminal diameter was suggested to be clinically significant for left mainstem disease. Although more severe stenoses were expected to upgrade urgency ratings, no thresholds were set for other vessels, since the clinical significance of obstruction is often determined in the context of both symptoms and results of non-invasive investigations for risk of ischaemic damage (ie, exercise electrocardiography [ECG] and nuclear imaging procedures).

Since patients being assessed for priority for treatment would have angiographically documented disease, the application of non-invasive tests is not to determine presence or absence of clinical CHD, but rather the degree of risk of ischaemia and the risks of delay. A simple division between "high risk" and "not high risk" was accordingly adopted. Non-invasive results were not included in rating patients in unstable angina classes IV–B and IV–C, which carry high risk of an early myocardial infarction. Examples of "high-risk" non-invasive test results are as follows: a high-risk score on the three-variable formal exercise ECG scoring system of Mark et al;[11] early and striking ST-segment depression (≥2 mm) on exercise ECG; hypotension during exercise testing;[12] and nuclear imaging

exercise or dipyridamole thallium scintigraphy.[13,14]

Other factors

Two further factors were incorporated into all case-histories: left ventricular function (grades 1 to 4); and expected procedure-related morbidity and mortality (high versus low/average) based on features other than ventricular dysfunction—eg, renal failure, and chronic airflow limitation. Statistical modelling showed the effects of changing grades of left ventricular function on urgency ratings to be consistent but small. According to rankings made by panelists and to their consensus recommendation, a high risk of procedure-related morbidity and mortality has little influence on urgency but a large one on decisions about whether it is appropriate to proceed—ie, whether the risk-benefit ratio of revascularisation is satisfactory.

Two other factors were incorporated into the case-history questionnaire only for cases of unstable angina with incomplete therapeutic response (panel classes IV-B and IV-C)—previous CABS, and recent myocardial infarction. Previous CABS was included because of practical constraints in providing urgent surgery, given the increased technical demands and operative time required for repeat procedures. Although these two factors had a definite impact on appropriateness ratings, neither had a consistent or large influence on urgency scores. The panelists recommended, however, that recent myocardial infarction should be considered on an individual basis, because of its potential to upgrade urgency in special cases (eg, post-thrombolysis).

Summary of consensus recommendations of the panel

The full text of the panel's consensus statement is available (from C. D. N.) on request. Some pertinent points are discussed here.

Any triage guidelines must complement the prudent exercise of clinical judgment, not supersede or supplant it. Fundamental to the Ontario system is the assumption that those at greater temporal risk of ischaemia-related adverse events deserve priority. The scheme is oriented only to rating the urgency of cases; it remains incumbent upon the practitioner to ensure that there are appropriate indications for surgery.

Symptom status is the key urgency determinant, with precedence also being given to patients with coronary stenoses that put large amounts of myocardium at risk of ischaemic damage, especially when corroborated by results of non-invasive tests. Impaired left ventricular function upgrades urgency slightly, albeit potentially affecting appropriateness of intervention by influencing the risk-benefit ratios. Other things being equal, higher-grade stenoses of affected vessels will take priority over lesser degrees of stenoses, but individual judgments are needed. Although high risk of procedure-related morbidity and mortality is a minor urgency determinant, it may well affect timing because of practical constraints (eg, when post-operative intensive care unit [ICU] beds are in such short supply that a prolonged ICU stay could cause cancellation of procedures for other persons at the same urgency ranking). Interval changes in any of the factors obviously necessitate re-ranking of the affected patient.

Emergency revascularisation (level 1) may apply to class IV-C unstable patients who present with recurrent despite maximum parenteral therapy and or use of an intra-aortic balloon pump. Level 2 ratings (within 24 h) apply primarily to patients with breakthrough ischaemic symptoms despite parenteral therapy, particularly if the coronary anatomical pattern suggests major risk of ischaemic injury. Patients presenting with unstable angina who respond well to medical therapy (panel class IV-A) vary between "semi-urgent" and "delayed" categories depending largely on the anatomical pattern and results of non-invasive tests (see table III).

For stable angina, if symptoms interfere with quality of life such that benefits of revascularisation clearly outweigh the risks, waiting times of more than 3 months are undesirable. However, if necessary, ratings move toward 7 (ie, up to 6 months' wait) for patients with Canadian Cardiovascular Society class I-II symptoms, low risk as indicated by results of non-invasive tests, normal left ventricular function, and limited coronary disease; most of these patients were deemed questionable or inappropriate candidates for surgical therapy by varying numbers of panelists.

Scoring system for urgency rating

A simple scoring table (table III) was developed as described above; it closely parallels the specific recommendations of the panel for particular angina classes. The summary score combines the regression constant for each angina class with the coefficients for anatomy. These scores clearly show the expected patterns for differences in severity or stability of angina classes and potential importance of anatomical lesions. To take account of high-risk of ischaemic event as indicated by non-invasive tests, the score should be upgraded by subtracting the coefficient shown for each angina class.

Left ventricular function can also be added to the scheme although the maximum possible difference in any case attributable to changes in left ventricular grade was 0·40. Thus presence of an impaired ventricle (grade 3 or 4) will upgrade the urgency score by no more than 0·20, whereas normal left ventricular function (grade 1) exerts an opposite effect of similar magnitude.

The standard errors attest to the precision of the scores with respect to the case-history ratings, and the good fits between the values predicted from the scoring table and actual trimmed means are shown by the magnitude of the typical and maximum residuals.

Discussion

American[2,8] and British[15] RAND panels have previously graded the appropriateness of indications for CABS, but not weighed issues of urgency and triage. Triage practices for patients requiring coronary bypass surgery or angioplasty have never been studied in a randomised controlled trial. Moreover, observational studies to determine predictors of perioperative and postoperative complications from CABS[16-18] do not take waiting times into account; the key outcomes in such studies—death or infarction—would in any case be expected to occur preoperatively when waiting times are excessive. The formal consensus process described above was therefore the best possible means of deriving guiding principles in this uncertain area of practice.

Ideally, the panel's approach should be validated by randomising patients either to conventional care or to

institutional queues ordered on the basis of our proposed system. However, such a trial is not feasible. Observational studies are nonetheless underway, drawing in part on the experience of a triage referral programme in Toronto that uses the scoring system outlined above.

The panelists sought to create a very simple system incorporating only essential objective clinical data. All things being equal, a doctor's response to a 65-year-old retired person with moderate angina of effort may be different from that to a 40-year-old labourer who is disabled by similar symptoms. However, such issues seem best left to the fiduciary judgment of the parties involved. Some interpractitioner variability in factor interpretation is also inevitable—ie, one cardiologist's class III angina may be another's class II.[18] The chances of these vagaries are perhaps small for the unstable angina categories developed by the panel (IV-A,B,C), which appeared practical and appropriate to triage decision-making. Nonetheless, the system is obviously dependent on the doctors' informed appraisals of patients' symptoms, and on reasonable trials of medical therapy for symptom control.

For some doctors an urgency rating system may be ethically discomfiting. However, for a typical case-history, the discrepancy between the panelists' highest and lowest urgency ratings was equivalent to differences in timing of 2 weeks for patients with severely unstable angina, and of at least 3 months for those with stable symptoms.[7] Thus practising without such a schema in places where there are long waiting lists for CABS or PTCA could be an ethical issue. With no common terminology and no urgency ranking system, inter-practitioner and interinstitutional differences are inevitable, cannot be identified for planning purposes, may be harmful to patients, and raise the issue of whether truly informed consent has been obtained from those who await revascularisation procedures. Moreover, the panel's goal was to cope with the reality of limited resources, without in any way countenancing the concept of lengthy waiting lists for revascularisation procedures.

Is our system applicable in other countries? The 1988 Ontario CABS rate of 42 per 100 000 persons is less than half the American national rate but about double the British rate, and international differences in doctors' views on surgical indications have been recorded.[19] Thus variability among nations exist in both the types of patients awaiting revascularisation and their waiting times. Our concern was the variability in queue-forming practices within a given health care system. Nonetheless, our experience shows how a formal consensus process can help set guidelines for identifying patients who deserve priority for revascularisation. Our scheme can be modified for use elsewhere by altering the time-frames attached to the urgency ratings, or by retaining only the scoring system to help select order of priority in surgical queues irrespective of average or target waiting time.

Revascularisation Panel— Cardiologists: R. S. Baigne, Sunnybrook Health Science Centre (co-chairman); Donald S. Beanlands, University of Ottawa Heart Institute; Neil Berman, Toronto Western Hospital; David Boris, Peel Memorial Hospital, Brampton; John A. Cairns, Hamilton General Hospital (co-chairman); David H. Fitchett, Royal Victoria Hospital, Montreal; Amin Haq, Toronto Western Hospital [deceased]; Allan Hess, York County Hospital, Newmarket; William Hughes, Peterborough Civic Hospital; James Swan, Scarborough Centenary Hospital; Allan Tinmouth, Scarborough General Hospital. Cardiac surgeons: B. S. Goldman, Sunnybrook Health Science Centre (co-chairman); John Gunstensen, Hamilton General Hospital; S. V. Lichtenstein, St Michael's Hospital; David Salter, Toronto Western Hospital; Richard D. Weisel, Toronto General Hospital. Consensus Methods Groups—Geoffrey M. Anderson, Department of Health Care and Epidemiology, University of British Columbia; Maria C. Bacchus, Toronto Hospital; A. Basinski, Sunnybrook Clinical Epidemiology Unit and Toronto Western Hospital; Linda Hunter, Toronto Cardiovascular Triage and Registry Program; Jonathan Lomas, Centre for Health Economics and Policy Analysis, McMaster University; Christopher D. Morgan, Sunnybrook Health Science Centre; C. D. Naylor (chairman), Sunnybrook Health Science Centre; Jerri Olak, Department of Thoracic Surgery, University of Toronto; M. M. Rachlis, consultant in epidemiology and program evaluation.

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CABG Priority Score

Anatomical Equivalent	Stable Angina		Unstable Angina*		
	Class I/Class II	Class III	Class IV A	Class IV B	Class IV C
Left main disese	5.40	4.85	4.75	3.40	2.15
2 vessel, 3 vessel + prox LAD	6.15	6.00	5.50	3.90	2.55
3 vessel disease (without prox LAD)	6.45	6.35	5.80	3.90	2.65
1 vessel + prox LAD	6.80	6.55	5.80	4.05	2.90
1 vessel, 2 vessel (without prox LAD)	6.95	6.65	6.15	4.15	3.05
Non-invasive testing**	-0.9	-0.75	-0.75	n/a	n/a

* Class IV A - resolved with increased therapy; Class IV B - resolved with increased therapy, recurrs with minimal activity; Class IV C - requires intravenous therapy for pain control

**high risk exercise EKG, high risk nuclear medicine study

Score: _____ Priority

1 - Immediately

2 - ≤ 24 hours

3 - ≤ 72 hours

4 - ≤ 14 days (same admission)

5 - ≤ 6 weeks

6 - ≤ 3 months

7 - ≤ 6 months

Appendix F

Coronary artery bypass graft surgery in Newfoundland and Labrador

Evidence

Études

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See related article page 1151

Abstract

Background: Newfoundland and Labrador, like other health care jurisdictions, is faced with widening gaps between the demands for health care and a strained ability to supply the necessary resources. The authors carried out a study to determine the rates of appropriate and inappropriate coronary artery bypass grafting (CABG) in the province and the waiting times for this surgery.

Methods: This retrospective cohort study was performed in the tertiary care hospital that receives all referrals for coronary angiography and coronary artery revascularization for Newfoundland and Labrador. By reviewing the hospital records, the authors identified 2 groups of patients: those in whom critical coronary artery disease was diagnosed on the basis of coronary angiography and who were referred for CABG between Apr. 1, 1994, and Mar. 31, 1995, and those who actually underwent the procedure during that period. By applying specific criteria developed by the RAND Corporation, the authors determined the appropriateness and necessity of CABG in each case. They also compared waiting times for CABG with optimal waiting times, as determined by a consensus-based priority score.

Results: A total of 338 patients underwent CABG during the study period. The cases were characterized by multivessel disease and late-stage angina symptoms. Almost all of the patients had high appropriateness scores (7–9), and nearly 95% had high necessity scores (7–9). However, during the study period, the waiting list increased by about 20%, because a total of 391 patients were referred by the weekly cardiovascular surgery conference; the authors identified these and an additional 31 patients as having necessity scores of 7 or more. Only 7 (23%) of 31 patients for whom CABG was considered very urgent underwent surgery within the recommended 24 hours, and only 30 (24%) of the 122 patients for whom CABG was considered urgent underwent surgery within the recommended 72 hours.

Interpretation: These results provide evidence that the cardiac surgery program in Newfoundland and Labrador is performing CABG in patients for whom surgical revascularization is highly appropriate and necessary. Access to CABG is less than ideal, however, since the waiting list continues to expand, and many patients wait beyond the recommended time for surgery.

Résumé

Contexte : Dans le domaine des soins de santé, Terre-Neuve et le Labrador font face, comme les autres provinces et territoires, à des écarts qui se creusent entre la demande et une capacité grevée de fournir les ressources nécessaires. Les auteurs ont réalisé une étude pour déterminer les taux de pontages aortocoronariens (PAC) appropriés et inutiles dans la province et la durée des périodes d'attente écoulées avant de subir cette intervention chirurgicale.

Méthodes : Cette étude rétrospective de cohorte a été réalisée dans l'hôpital de soins tertiaires qui reçoit tous les patients que l'on envoie subir une coronarographie et une revascularisation de l'artère coronaire à Terre-Neuve et au Labrador. En étudiant les dossiers de l'hôpital, les auteurs ont défini deux

groupes de patients : ceux chez lesquels on a diagnostiqué une coronaropat critique à la suite d'une angiographie coronarienne et que l'on a envoyé su un PAC entre le 1er avril 1994 et le 31 mars 1995, et ceux qui ont vraiment si l'intervention au cours de la même période. En utilisant des critères particuli mis au point par la RAND Corporation, les auteurs ont déterminé la pertiner et la nécessité du PAC dans chaque cas. Ils ont aussi comparé les périodes d' tente aux périodes d'attente optimales déterminées en fonction de priori établies par consensus.

Résultats : Au total, 338 patients ont subi un PAC pendant la période d'étude. L multiples vaisseaux atteints et les symptômes angineux au stade final caracté saient les cas. Chez presque tous les patients, les résultats de pertinence étaie élevés (7–9) et dans presque 95 % des cas, l'intervention était très nécessai (7–9). Au cours de la période d'étude, toutefois, la liste d'attente s'est allongé d'environ 20 % parce qu'au total, 391 patients ont été présentés à la suite de table ronde hebdomadaire sur la chirurgie cardiovasculaire; les auteurs o déterminé que chez ces patients et chez 31 autres, la cote de nécessité a teignait 7 ou plus. Seulement 7 (23 %) des 31 patients chez lesquels on a jug qu'un PAC était très urgent ont subi l'intervention chirurgicale dans le dél recommandé de 24 heures et 30 (24 %) seulement des 122 patients che lesquels on a jugé le PAC urgent ont subi l'intervention chirurgicale dans l délai recommandé de 72 heures.

Interprétation : Ces résultats démontrent que dans le cadre du programme d chirurgie cardiaque à Terre-Neuve et au Labrador, on pratique des PAC che des patients pour lesquels la revascularisation chirurgicale est très pertinente e nécessaire. L'accès au PAC n'est toutefois pas idéal, car les listes d'attente con tinuent de s'allonger et beaucoup de patients attendent plus longtemps que l délai recommandé pour subir une intervention chirurgicale.

Despite the evidence supporting coronary revascularization, controversy exists regarding the appropriate use of coronary artery bypass grafting (CABG) in clinical practice. This debate relates to overuse in some regions and underuse in others and is the result of inconsistent descriptions of patient outcomes,[1] observed variations in practice,[2,3] different ratings of appropriateness,[4] escalating costs,[5] rationing of health care services[6,7] and recent media attention.[8]

The province of Newfoundland and Labrador, like other health care jurisdictions, is faced with widening gaps between the demands for health care and a strained ability to supply the necessary resources. Effective delivery of CABG to the community implies that the surgery be performed in appropriate patients, that waiting periods be reasonable and that the patients who need the procedure actually receive it. We carried out a study to determine the rates of appropriate and inappropriate CABG and the waiting times for this surgery in Newfoundland and Labrador over a 12-month period.

Methods

The study protocol was approved by the Human Investigation Committee at Memorial University of Newfoundland, St. John's.

Patient selection

We reviewed the records of the tertiary care hospita that receives all referrals for coronary angiography anc coronary artery revascularization for Newfoundland anc Labrador. We identified 2 groups of patients: those with a diagnosis of critical coronary artery disease establishec by coronary angiography[9] who were referred for CABG between Apr. 1, 1994, and Mar. 31, 1995, and those who actually underwent the procedure during that period (many of whom were already on the waiting list for CABG at the beginning of the study period). We obtained the patients' medical records, including pertinent documents from referring hospitals, from the Health Care Corporation of St. John's. We used a modified medical record abstraction form[9] to capture the data required to determine the appropriateness, necessity and priority of CABG. The data were collected by experienced research nurses and data abstractors trained to use the form. The information collected included demographic characteristics such as age, sex and date of coronary angiography. Additional data included angina symptoms, cardiovascular history, cardiac medications and coronary artery anatomy. We also collected data on noninvasive testing, such as exercise stress testing and assessments of left ventricular function.

We classified angina symptoms, coronary artery anatomy and indications for CABG on the basis of the data collected and subsequently reviewed these classifications for accuracy. All abstracted records were reviewed by 2 of us (G.A.F. and P.S.P.) for completeness and consistency. In addition, these 2 authors independently scored each record for the appropriateness and necessity of CABG according to the RAND Corporation criteria.[9] The appropriateness and necessity scores were subsequently compared, and discrepancies were settled by consensus.

Whenever possible, for each case we obtained photocopies of notes from the cardiac catheterization procedure, the cardiovascular surgery conference and the surgery itself and attached these documents to the data record form. In addition, discharge summaries and letters of consultation as well as results of investigations such as stress tests and echocardiography were attached to the form.

Definitions

The definitions for unstable angina, angina class, asymptomatic coronary artery disease, significant coronary artery disease, maximum medical therapy, results of noninvasive tests, levels of operative risk and contraindications to CABG were those approved by the Canadian panel that developed the scoring instrument.[9,10]

Scoring of appropriateness and necessity

After collecting the data, we assessed each case for the appropriateness and necessity of CABG using a predetermined criterion-based, validated scoring system developed by the RAND Corporation and adapted for the Canadian population.[9]

A procedure was deemed appropriate if the expected health benefits exceeded the expected negative consequences by a margin that would lead the physician to regard the procedure as worth doing, exclusive of monetary costs.[9] A procedure was deemed necessary if the physician would feel obligated to recommend this procedure as the best clinical option available, given the high probability of a clinically important benefit in patients with that presentation.[9] Thus, the necessity ratings include a more stringent risk–benefit assessment than do the appropriateness ratings, and, by definition, if a procedure is considered necessary it must first be considered appropriate.

Appropriateness was scored on an ordinal scale from 1 (extremely inappropriate) to 9 (extremely appropriate). In general terms, a score of 1 to 3 indicates inappropriate, 4 to 6 intermediate and 7 to 9 appropriate. The same ratings were used for the necessity scores.

Priority scoring

Using a priority score developed by consensus,[11,12] we ranked patients waiting for CABG according to need. The priority ranking was determined by the pattern or severity of angina symptoms, the coronary artery anatomy and the results of noninvasive tests of ischemic risk.[12] The cases were categorized 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 elective list (should undergo surgery within 6 weeks) and delayed elective list (should undergo surgery within 6 months).

By comparing this categorization with the length of time the patients actually waited for CABG, we were able to make an indirect assessment of the efficiency with which the cardiac surgery program delivers CABG in the province.

Results

Study population

Coronary angiography was performed in 1604 patients during the study period. Of these, 1082 had critical coronary artery disease involving at least one artery. Percutaneous transluminal coronary angioplasty (PTCA) was performed in 266 of these patients. Of the 816 patients with critical coronary artery disease who did not undergo PTCA, 58 had a contraindication to surgery, and 9 had incomplete medical records. Of the remaining 749 patients, 391 (279 men and 112 women with a mean age of 61.9 [SD 10.2] years) were referred for CABG, and 358 (252 men and 106 women with a mean age of 57.6 [SD 11.2] years) were treated medically. The clinical characteristics of the 2 groups are shown in Table 1.

The average waiting time for CABG among the 391 patients referred for this procedure during the study period was 33 (SD 63.5) days (range less than 1 hour to 397 days). The last CABG procedure for this group was performed on Oct. 14, 1995. Of the 391 patients, 301 (77.0%) had symptoms compatible with class IV angina, and 71 (18.2%) had class III angina symptoms. A total of 328 patients (83.9%) were receiving maximum medical therapy at the time of coronary angiography. Over half (222 [56.8%]) had triple-vessel disease, and 61 (15.6%) had disease of the left main coronary artery.

During the 12-month study period only 338 patients (242 men and 96 women with a mean age of 61.0 [SD 10.6] years) actually underwent CABG (Table 2). Of these, 208 had been on the waiting list before Apr. 1, 1994. Most presented with unstable angina (252 [74.6%])

or had persistent ischemia following myocardial infarction (33 [9.8%]). A total of 252 (74.6%) had left main artery or triple-vessel disease, and 289 (85.5%) were receiving maximal medical therapy.

Appropriateness of CABG

The appropriateness and necessity scores were high. Of the 338 procedures, 334 (98.8%) were considered appropriate and 317 (93.8%) were considered necessary. There were no cases in which CABG was considered inappropriate (Table 2).

Table 1: Clinical characteristics[*†] of patients in Newfoundland and Labrador in whom critical coronary artery disease was diagnosed by angiography over a 1-year period and who did not undergo percutaneous transluminal coronary angioplasty

Characteristic	Group; no. (and %) of patients: Referred for CABG surgery *n = 391*	Medical treatment *n = 358*
Angina		
None	9 (2.3)	54 (15.1)
Class I	2 (0.5)	54 (15.1)
Class II	8 (2.0)	35 (9.8)
Class III	71 (18.2)	42 (11.7)
Class IVA	77 (19.7)	136 (38.0)
Class IVB	81 (20.7)	26 (7.3)
Class IVC	143 (36.6)	11 (3.1)
Indication for CABG		
Stable angina	49 (12.5)	80 (22.3)
Unstable angina	275 (70.3)	153 (42.7)
Acute MI	4 (1.0)	2 (0.6)
Post MI	43 (11.0)	91 (25.4)
Asymptomatic	3 (0.8)	28 (7.8)
Near sudden death	1 (0.2)	3 (0.8)
Complications of PTCA or CA	5 (1.3)	0 (0.0)
Valve surgery	11 (2.8)	1 (0.3)
Coronary anatomy		
Protected left main artery	1 (0.2)	2 (0.6)
Unprotected left main artery	60 (15.3)	1 (0.3)
3-vessel disease	222 (56.8)	48 (13.4)
2-vessel disease + PLAD	52 (13.3)	46 (12.8)
2-vessel disease	35 (9.0)	67 (18.7)
1-vessel disease + PLAD	15 (3.8)	46 (12.8)
1-vessel disease	6 (1.5)	148 (41.3)
Ejection fraction, %		
> 35	287 (73.4)	285 (79.6)
15–35	80 (20.5)	63 (17.6)
< 15	20 (5.1)	8 (2.2)
No data	4 (1.0)	2 (0.6)
Operative risk		
Normal or low	250 (63.9)	268 (74.9)
Moderate or high	101 (25.8)	81 (22.6)
Very high	40 (10.2)	9 (2.5)

Note: CABG = coronary artery bypass grafting, MI = myocardial infarction, PTCA = percutaneous transluminal coronary angioplasty, CA = coronary angiography, PLAD = proximal left anterior descending artery.

Waiting period

Although 391 patients were referred for CABG dur the study period, only 338 underwent surgery; thus, waiting list increased by 53 patients.

Table 2: Clinical characteristics of the 338 patients who underwent CABG during the 1-year study period[*]

Characteristic	No. (and %) of patients
Angina	
None	6 (1.8)
Class I	1 (0.3)
Class II	5 (1.5)
Class III	50 (14.8)
Class IVA	66 (19.5)
Class IVB	67 (19.8)
Class IVC	143 (42.3)
Indication for CABG	
Stable angina	34 (10.1)
Unstable angina	252 (74.6)
Acute MI	3 (0.9)
Post MI	33 (9.8)
Asymptomatic	2 (0.6)
Near sudden death	1 (0.3)
Complications of PTCA or CA	5 (1.5)
Valve surgery	8 (2.4)
Coronary anatomy	
Protected left main artery	1 (0.3)
Unprotected left main artery	62 (18.3)
3-vessel disease	189 (55.9)
2-vessel disease +PLAD	49 (14.5)
2-vessel disease	24 (7.1)
1-vessel disease +PLAD	11 (3.2)
1-vessel disease	2 (0.6)
Ejection fraction, %	
> 35	250 (74.0)
15–35	63 (18.6)
< 15	21 (6.2)
No data	4 (1.2)
Stress test result	
Very positive	161 (47.6)
Not very positive	28 (8.3)
No data	149 (44.1)
Operative risk	
Normal or low	217 (64.2)
Moderate or high	85 (25.1)
Very high	36 (10.6)
Appropriateness score for CABG†	
1–3	0 (0.0)
4–6	4 (1.2)
7–9	334 (98.8)
Necessity score for CABG†	
1–3	4 (1.2)
4–6	17 (5.0)
7–9	317 (93.8)

*Of these patients, 289 (85.5%) were receiving maximum medical therapy at the time of CABG.

†1 = extremely inappropriate or unnecessary, 9 = extremely appropriate or necessary.[9] See Methods.

In addition, using the RAND Corporation criterion of a necessity score of 7 or higher as an indication for surgery,[9] we identified another 31 patients (i.e., 422 in all) for whom CABG was considered necessary.

The length of time spent on the waiting list for each category of patient is shown in Fig. 1 (for patients referred for CABG during the study period). On the basis of the priority scores, CABG was considered very urgent for 31 patients, of whom 7 (23%) underwent the surgery within the recommended time. The proportions of patients in the other groups who underwent CABG within the recommended time were as follows: 30/122 (24%) in the urgent group, 56/87 (64%) in the semi-urgent group, 49/98 (50%) in the short wait group and 40/53 (75%) in the delayed wait group.

To our knowledge, 4 patients died while awaiting CABG during the study period.

Interpretation

We found that, for the period under review, the cardiac surgery program in Newfoundland and Labrador performed CABG predominantly in patients with late-stage angina symptoms and multivessel coronary artery disease. In addition, bypass surgery was performed in patients for whom the surgery was considered highly appropriate and necessary. However, we did observe substantial delays relative to suggested waiting periods.

Most of the patients in this study presented with advanced disease, 587 (78.4%) of the 749 with class III or IV angina symptoms. Unfortunately, the inconsistent reporting of angina symptoms in the literature[13–16] precludes valid comparisons of angina classification between studies. A total of 493 (65.8%) of the 749 patients in the study cohort had angiographic evidence of multivessel coronary artery disease involving the left main coronary artery or the proximal left anterior descending artery. This finding is similar to the proportion of patients with multivessel disease with or without left main or left anterior descending artery involvement reported in other studies (54% to 62%).[13–15]

Among the 338 patients who underwent CABG, we did not observe any cases in which the surgery was considered inappropriate. In comparison, the reported rate of inappropriate procedures at other centres varies from 2% to 16%.[9] Furthermore, 94% of the CABG procedures in our study were considered necessary according to RAND Corporation criteria.[9] This rate exceeds other Canadian and US reports of 70% to 83%.[15,17]

Despite the delivery of highly appropriate and necessary surgery there were still delays for some patients awaiting CABG. We observed considerable discrepancies between recommended and actual waiting times for surgery. Although some patients underwent surge within the optimal period, an average of about 50% of p tients in each category were still waiting for surgery at t end of their recommended waiting period. There was ev dence, however, that cases were given priority on the bas of urgency, since patients with class IV angina sympton underwent the procedure sooner than patients with le severe angina.

The failure to achieve optimal waiting times resulte at least in part, from the constant addition of urgent cas to the top of the waiting list, thus consuming a limited re source. In addition, the total number of CABG proce dures performed annually was far less than the number c

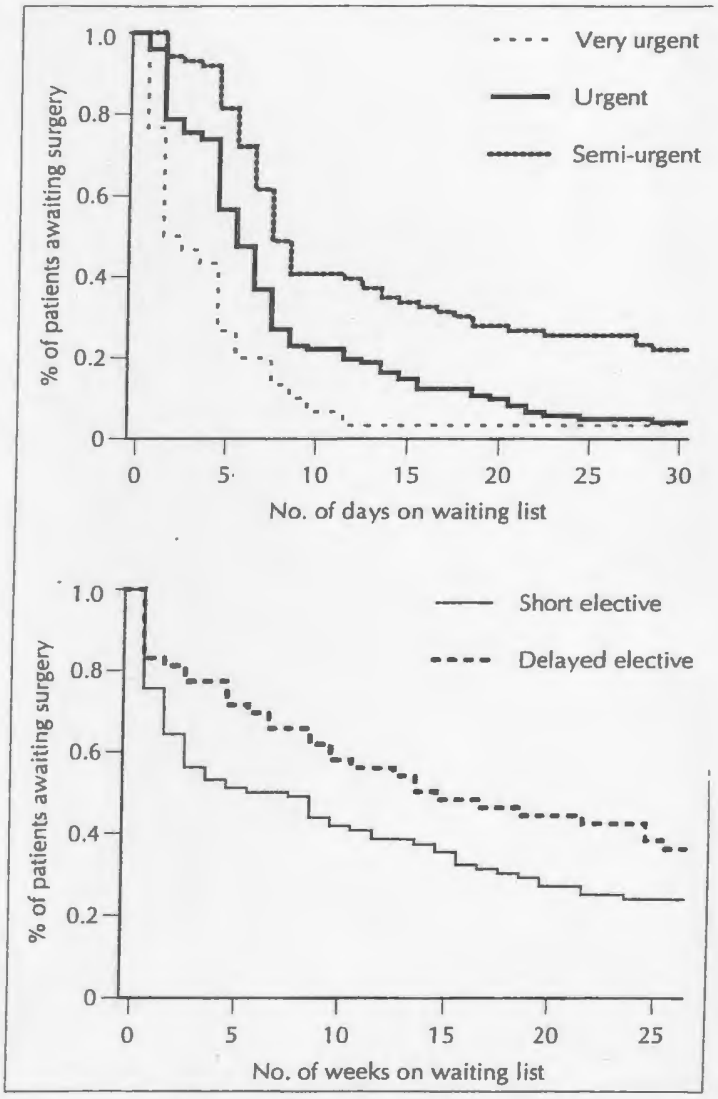

Fig. 1: Length of time on waiting list for coronary artery bypass graft surgery for patients referred between Apr. 1, 1994, and Mar. 31, 1995, in Newfoundland and Labrador. The categories refer to the recommended priority of the cases: very urgent, surgery should be performed within 24 hours; urgent, within 72 hours; semi-urgent, within 14 days during the same hospital stay; short elective, within 6 weeks; delayed elective, within 6 months.

patients who required surgery, as determined by either the cardiovascular surgery conference (391) or the RAND Corporation criteria (422). These factors select for patients with more advanced coronary artery disease and may delay access to CABG for others. Additional reasons for delays include economic restraint, lack of access to critical care beds, lack of surgical assistants and a limited number of cardiac surgeons.

Limitations

The predominant limitation of our study arises from the use of a retrospective chart audit for data collection. The abstraction of data was therefore dependent on the accuracy of the information recorded at the time of the original consultation, coronary angiography, surgical procedure and follow-up visits. To minimize these problems, we used properly trained data abstractors and a standardized, validated data abstraction record adapted for the Canadian population.

Conclusions

The patient profile and indications for CABG in our study show that in 1994 and 1995, the cardiac surgery program in Newfoundland and Labrador was providing revascularization to patients with late-stage angina symptoms and advanced coronary artery disease. However, despite the performance of appropriate and necessary surgery in patients with advanced disease, the waiting list for bypass surgery continued to expand, and optimal waiting times for individual patients were often exceeded. This discrepancy has prompted the provincial government to use specific criteria (i.e., RAND Corporation necessity score of 7 or higher) to estimate the annual needs for CABG. This policy warrants investigation to determine its effect on the delivery of CABG.

Failure to perform CABG quickly in urgent cases may contribute to excess illness, unnecessary hospital costs and patient dissatisfaction. Furthermore, there is likely a larger group of symptomatic patients with less advanced disease whose condition is stable for whom CABG may be delayed. The long-term effects on this subgroup in terms of death, illness and lost productivity are unknown.

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Appendix G

Need for coronary artery bypass grafting in Newfoundland and Labrador: The impact of increased demand

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GM Kent, L Power, DM Gregory, et al. Need for coronary artery bypass grafting in Newfoundland and Labrador: The impact of increased demand. Can J Cardiol 2004;20(4):399-404.

BACKGROUND: In the past deçade, growth of coronary revascularization in Canada has been substantial. It was hypothesized that as coronary angiography (CA) rates increased, referral for necessary coronary artery bypass grafting (CABG) would also increase, and include patients with multivessel disease and class I to III angina who required elective surgery. Furthermore, it was proposed that the number of CABG surgeries needed would increase at a similar rate to that of CA.

METHODS: An incident cohort of patients who received CA in 1998/1999 was identified, and the group referred for CABG was followed. Clinical characteristics, appropriateness and necessity scores using specific criteria, and waiting times were evaluated and compared with a similar cohort from 1994/1995. Utilization data for coronary revascularization procedures from 1994 to 2002 were reviewed.

RESULTS: Between 1994/1995 and 1998/1999, the number of CAs per year increased by 37%. The inappropriateness rate for CA was 4% in 1998/1999. The proportion of patients diagnosed with critical coronary artery disease increased from 68% in 1994/1995 to 74% in 1998/1999. The number referred for CABG increased by 48%, and the number for percutaneous transluminal coronary angioplasty (PTCA) increased by 137%. The increase in the number referred for CABG was attributable to the increase in the number of patients with less severe symptoms who required delayed elective CABG. The necessity rate for CABG in the referred group was 94% in 1994/1995 and 95% in 1998/1999. A further 91 patients were identified who needed CABG but did not receive it, 86% of whom had PTCA. From 1999 to 2002, the annual growth rate in those referred for CABG was higher than the growth rate for CA.

CONCLUSIONS: With the growth in CA, the rate of discovery of high risk coronary anatomy actually increased. Growth in CABG volume was attributable to growth in the need for elective surgery in patients with class I to III angina. The rate of CABG increased disproportionately to the rate of CA, despite higher rates of PTCA with stenting. It is likely that the demand for CABG will continue to rise steadily, as expansion of angiography occurs, and may be higher than expected from the growth in CA.

Key Words: *Coronary angiography; Coronary artery bypass grafting; Medications; Necessity scores; Waiting times*

Les besoins de pontages aortocoronariens à Terre-Neuve et au Labrador : Les effets de l'augmentation de la demande

HISTORIQUE : Depuis dix ans, les revascularisations coronariennes ont connu une augmentation substantielle au Canada. On postule qu'avec l'augmentation des taux d'angiographie coronarienne (AC), les aiguillages pour un pontage aortocoronarien (PAC) nécessaire augmenteraient aussi, et incluraient des patients atteints d'une maladie pluritronculaire ou d'une angine de classe I à III qui auraient eu besoin d'une intervention non urgente. De plus, il est proposé que le nombre d'opérations pour un PAC nécessaire augmenterait à un taux similaire à celui des AC.

MÉTHODOLOGIE : Des cohortes incidentes de patients qui avaient subi une AC en 1998-1999 ont été repérées, et le groupe aiguillé pour un PAC a été suivi. Les caractéristiques cliniques, la pertinence et les indices de nécessité calculés à l'aide de critères précis, de même que les temps d'attente, ont été évalués et comparés à ceux d'une cohorte similaire de 1994-1995. Les données d'utilisation des interventions de revascularisation coronarienne effectuées entre 1994 et 2002 ont été examinées.

RÉSULTATS : Entre 1994-1995 et 1998-1999, le nombre d'AC par année a augmenté de 37 %. Le taux de non-pertinence d'AC s'élevait à 4 % en 1998-1999. La proportion de patients recevant un diagnostic de coronaropathie chronique est passée de 68 % en 1994-1995 à 74 % en 1998-1999. Le nombre d'aiguillages pour un PAC a augmenté de 48 %, et le nombre d'aiguillages pour angioplastie transluminale percutanée (ATP), de 137 %. L'augmentation du nombre de patients aiguillés pour un PAC a été attribuée à celle du nombre de patients présentant des symptômes moins graves et qui avaient besoin d'un PAC non urgent. Le taux de nécessité pour un PAC au sein du groupe aiguillé s'élevait à 94 % en 1994-1995 et à 95 % en 1998-1999. On a repéré 91 patients qui auraient eu besoin d'un PAC mais qui ne l'ont pas subi, mais 86 % d'entre eux avaient subi une ATP. Entre 1999 et 2002, le taux de croissance annuelle des personnes aiguillées pour un PAC était plus élevé que le taux de croissance des AC.

CONCLUSIONS : Étant donné la croissance des AC, le taux de découverte d'anatomie coronarienne à haut risque a augmenté. La croissance du volume de PAC était attribuable à la croissance du besoin d'intervention non urgente chez des patients atteints d'angine de classes I à III. Le taux de PAC a augmenté de manière non proportionnelle au taux d'AC, malgré des taux plus élevés d'ATP avec extenseur. Il est probable que la demande de PAC continue d'augmenter régulièrement, tandis que le nombre d'angiographies augmente, et il pourrait être plus élevé qu'on ne le prévoirait d'après la croissance de l'AC.

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In 1994/1995, an evaluation of the cardiac surgery program in Newfoundland revealed that the coronary artery bypass grafts (CABGs) performed were highly appropriate and necessary, but that access to CABG was not ideal, the waiting list was high and many patients waited beyond the recommended time for surgery (1). As a result, the government of Newfoundland and Labrador agreed to fund CABGs, based on need and the size of the waiting list. The number of CABGs to be funded was derived from the referral rate by cardiologists for CABG, and justified by the similarity with the rate based on the number of patients with high RAND Corporation necessity scores for CABG identified after coronary angiography (CA) (1). The number was estimated at 422 per year, plus an additional 40 per year to reduce the waiting list, a combined rate of 116 per 100,000 individuals older than 20 years of age.

Benchmarking needs for CABG may be rendered unreliable if the level of demand for CABG is itself inappropriate (2). Demand may increase if more patients are referred for angiography by internists and cardiologists, including patients with less advanced disease (2,3). Increased capacity for performing CABG also has the potential, through supply-induced demand, to lead to inappropriate overuse. On the other hand, demand for CABG may decrease if new efficacious coronary revascularization procedures are introduced, similar to what happened after 1995 when percutaneous transluminal coronary angioplasty (PTCA) with stenting started and dramatically changed practice (4).

In view of the restricted access to CABG, the high proportion of acutely ill patients and the high necessity rate in those referred for CABG in 1994/1995, we proposed the hypotheses that, as CA rates increased, rates of referral for CABG would also increase and the proportion of patients with less symptomatic disease would be higher, but the necessity scores would not deteriorate. These hypotheses were tested in an incident cohort who received CA in 1998/1999 using the same methods as in 1994/1995 (1).

Need for CABG was again defined as the referral rate from cardiology, and this rate was compared to that based on an objective scale for necessity that was applied to patients after CA (5). We suggested that the number of CABGs needed would increase at the same rates as CA, and assessed CA and coronary revascularization utilization data from 1998 to 2002.

METHODS

The study protocol was approved by the Human Investigation Committee at Memorial University of Newfoundland, St John's.

Utilization data

The records on CA, PTCA and CABG at the Cardiac Program of the Health Care Corporation of St John's were reviewed to determine the referral rates, utilization rates and wait lists for these procedures from 1994 to 2002. This program is the sole intraprovincial source of these services in Newfoundland and Labrador, which had 402,000 persons 20 years of age and older in 1999.

Data collection

From August 1, 1998, to July 31, 1999, a research nurse attended the cardiac catheterization laboratory, and an incident cohort of all patients having diagnostic CA during that year was identified. Demographic, clinical and diagnostic test data were collected to determine the appropriateness and necessity of CA (5). Records were kept 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 coronary artery disease. Priority for CABG was determined and waiting times for CABG were recorded. Patients who were referred for CABG were assessed for the appropriateness and necessity of CABG (6). Data from 1998/1999 were compared with those collected in 1994/1995.

The data were collected by a trained, experienced research cardiology nurse (GMK) and by a Masters student in clinical epidemiology (LP). The information collected included demographic characteristics such as age, sex and date of CA. Additional data included angina symptoms, cardiovascular history, cardiac medications and coronary artery anatomy. Data on non-invasive testing, such as exercise stress testing and assessments of left ventricular function, were also collected.

Angina symptoms, coronary artery anatomy and indications for CA or CABG were classified on the basis of the data collected, and each record was scored for the appropriateness and necessity of CA, CABG or PTCA according to the RAND Corporation criteria (5,6). Appropriateness and necessity scores inconsistent with the clinical data were reviewed by the authors (GCM and PSP), and discrepancies were settled by consensus.

Whenever possible, 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, were collected for review on the study data record form.

Definitions

The definitions for unstable angina, angina class, asymptomatic coronary artery disease, significant coronary artery disease, maximum medical therapy, results of noninvasive tests, level of operative risk and contraindications to CABG were approved by the Canadian panel that developed the scoring instrument (5,6).

Scoring of appropriateness and necessity

Data on each CA case were reviewed for appropriateness of angiography, and each case who had critical coronary artery disease was then scored for the appropriateness and necessity of CABG using predetermined criterion-based, validated scoring systems developed by the RAND Corporation and adapted for the Canadian population (5,6).

A procedure was deemed appropriate if the expected health benefits exceeded the expected negative consequences by a margin that would lead a physician to regard the procedure as worthwhile, exclusive of monetary costs. A procedure was deemed necessary if a physician felt obligated to recommend this procedure as the best clinical option available, given the high probability of a clinically important benefit in patients with that presentation. Thus, the necessity ratings included a more stringent risk-benefit assessment than did the appropriateness ratings; by definition, if a procedure is considered necessary, it must first be considered appropriate. Appropriateness was scored on an ordinal scale from 1 (extremely inappropriate) to 9 (extremely appropriate). In general terms, a score of 1 to 3 indicates inappropriate, 4 to 6 indicates intermediate, and 7 to 9 indicates appropriate. The same ratings were used for the necessity scores.

Priority scoring

Using a priority score developed by consensus, patients referred for CABG were ranked according to need (7). The priority ranking was determined by the pattern or severity of angina symptoms, the

TABLE 1
Characteristics of patients who underwent diagnostic coronary catheterization – considered appropriate, uncertain or inappropriate – in 1998/1999

Characteristic	Appropriate (n=1534) N (%)	Uncertain (n=457) N (%)	Inappropriate (n=80) N (%)
Age >75 years	57 (4)	126 (28)	2 (3)
Maximal medical therapy	1236 (80)	198 (43)	34 (43)
Exercise stress test			
Very positive	335 (22)	31 (7)	0 (0)
Positive	550 (36)	194 (42)	8 (11)
Indication for CA			
Chronic stable angina	472 (31)	174 (38)	27 (34)
Unstable angina	642 (42)	117 (26)	2 (3)
Acute MI/post MI angina	321 (21)	49 (11)	2 (3)
Chest pain (uncertain origin)	24 (2)	24 (5)	48 (60)
Silent ischemia	25 (2)	4 (1)	0 (0)
Other	50 (3)	89 (19)	1 (1)
Ejection fraction			
>35%	1216 (88)	331 (79)	70 (95)
15-35%	143 (10)	63 (14)	3 (4)
<15%	23 (2)	23 (6)	1 (1)
Coronary anatomy			
Protected left main	7 (1)	6 (1)	0 (0)
Unprotected left main	83 (5)	18 (4)	0 (0)
3-vessel disease	417 (27)	108 (24)	6 (8)
2-vessel disease with proximal LAD	125 (8)	34 (7)	2 (3)
2 vessels, no proximal LAD	194 (13)	60 (13)	3 (4)
1 vessel with proximal LAD	129 (8)	20 (4)	1 (1)
1 vessel, no proximal LAD	269 (18)	63 (14)	8 (10)
No critical CAD	309 (20)	147 (32)	60 (75)

CA Coronary angiography; CAD Coronary artery disease; LAD Left anterior descending artery; MI Myocardial infarction

coronary artery anatomy and the results of noninvasive tests of ischemic risk. The cases were categorized as follows: very urgent (patient should undergo surgery within 24 h), urgent (should undergo surgery within 72 h), semi-urgent (should undergo surgery within 14 days during the same hospital stay), short elective list (should undergo surgery within six weeks) and delayed elective list (should undergo surgery within six 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 the province of Newfoundland and Labrador.

RESULTS

CA

Between 1994/1995 and 1998/1999, the number of diagnostic CAs increased by 37% (from 1604 to 2196) and there were 134 persons on the waiting list for CA at the end of September 1999. By 1999, the cardiac catheterization laboratory was working at full capacity, which explains why the annual number of CAs done in 2000/2001(N=2258) increased by only 2.8% over 1998/1999, but the waiting list had increased to 343. A second cardiac catheterization laboratory was opened in 2002, with funding approved because of the increased wait list.

TABLE 2
Clinical characteristics of patients diagnosed by coronary angiography with critical coronary artery disease in 1994/1995 and 1998/1999

	1995 (N=1073) Mean (SD)	1999 (N=1625) Mean (SD)	P
Age, years	60 (±11)	61 (±11)	NS
	N (%)	N (%)	
Male	760 (71)	1152 (71)	NS
Diabetes mellitus	–	–	452 (28)
Angina class			
No angina/uncertain	69 (6.4)	117 (7)	NS
Class I to II	108 (11.9)	131 (8)	NS
Class III	146 (13.5)	534 (33)	<0.0001
Class IV	750 (69.3)	843 (52)	<0.0001
Very positive stress test	436 (40)	326 (20)	<0.0001
Ejection fraction <35%	268 (25)	226 (14)	<0.0001
Coronary anatomy			
Left main	72 (7)	119 (7)	NS
3 vessels	328 (30)	568 (35)	NS
2 vessels	314 (29)	438 (27)	NS
1 vessel	359 (33)	500 (31)	NS

Of 2071 CAs assessed for appropriateness using the RAND criteria in 1998/1999, 74% (N=1534) were appropriate, 22% (N=457) were uncertain and 4% (N=80) were inappropriate. The criteria could not be applied in 125 patients. In the inappropriate group, the majority (60%) were CAs for chest pain of uncertain etiology (Table 1). Cases in the uncertain group, compared with the appropriate group, were more likely to be over 75 years of age (28% versus 4%), less likely to have unstable angina as the indication for CA (26% versus 42%), more likely to have other reasons (particularly heart failure) as the indication for CA (19% versus 3%), and less likely to have a very positive stress test (12% versus 35%) and to be on maximal medical therapy (43% versus 81%).

By 1998/1999, the threshold for CA had been lowered to include more patients with class I to III angina, although the proportion with critical coronary disease, a measure of prudent use of CA, was a little higher than in 1994/1995: 1082 of 1604 (68%) CA patients were diagnosed with critical disease in 1994/1995, whereas the proportion had increased to 74% (1625 of 2196) in 1998/1999. Comparison of these two groups of patients with critical stenoses revealed that, although age, proportion of males and coronary anatomy was the same, the later cohort was characterized by significantly higher proportions with class III angina (33% versus 14%), lower proportions with very positive stress tests (20% versus 40%) and lower proportions with ejection fractions less than 0.35 (14% versus 25%) (Table 2).

Management of critical coronary artery disease

In 1994/1995, 391 of 1073 (36%) patients with critical coronary disease were referred for CABG, 25% (N=266) were referred for PTCA, revascularization was contraindicated in 5% (N=58) and 33% (N=358) were treated with medical therapy. Charts were not available for nine patients. By 1998/1999, practice patterns had changed – of 1625 patients with critical

TABLE 3
Clinical characteristics of patients referred for coronary artery bypass graft (CABG) in 1994/1995 and 1998/1999

	1994/1995 (N=391) Mean (SD)	1998/1999 (N=578*) Mean (SD)	P
Age (years)	62 (10)	62 (9)	NS
	N (%)	N (%)	
Male	279 (71)	445 (77)	0.05
Angina class			
No, I or II	19 (5)	67 (12)	0.05
III	71 (18)	248 (43)	<0.0001
IV a	77 (20)	24 (4)	<0.0001
IV b or c	224 (57)	239 (41)	<0.0001
Very positive stress test	198 (51)	154 (27)	<0.0001
Ejection fraction <0.35	100 (26)	90 (16)	0.0001
Maximal medical therapy	289 (86)	439 (76)	NS
Coronary anatomy			
Left main	61 (16)	97 (17)	NS
3 vessels	222 (57)	348 (60)	NS
2 vessels with PLAD	52 (13)	71 (12)	NS
2 vessels without PLAD	35 (9)	39 (7)	NS
1 vessel with PLAD	15 (4)	11 (2)	NS
1 vessel without PLAD	6 (1)	12 (2)	NS
Delayed elective priority for surgery	53 (14)	201 (41)	<0.0001

**This includes 61 patients who had repeat coronary angiographies because they were on the CABG wait list for longer than six months. PLAD Proximal left anterior descending artery*

disease, the proportion referred for PTCA increased to 39% (N=631), only 24% (N=397) were primarily treated with medical therapy, and revascularization was contraindicated in a further 7% (N=117), who were then treated medically. The proportion referred for CABG remained the same (36%; N=578), although repeat CAs for patients delayed on the CABG wait list for longer than six months accounted for 61 cases.

The clinical characteristics of the 1998/1999 cohort referred for CABG differed from the 1994/1995 cohort (Table 3) in that there was a shift toward patients who were less acutely ill: the proportion with class III angina was higher (43% versus 18%), the proportion on maximal therapy was lower (76% versus 86%) and the proportion considered elective (CABG to be performed between six weeks and six months) was higher (41% versus 14%). In fact, the increase in the number of patients referred for CABG could be attributed to the increase in the number of patients recommended for elective surgery.

This shift toward the less acutely ill was facilitated by the growth in PTCA. In 1998/1999, PTCA was used predominantly to treat the more acutely ill: 64% (N=405) of those referred for PTCA had unstable angina and 81% were on maximal medical therapy. A substantial number with less limited disease received PTCA: 26% (N=170) had left main, triple vessel, two vessel with proximal LAD disease. The comparable figures in 1994/1995 were as follows: 86% (N=289) who had a PTCA procedure had unstable angina, 86% (N=249) were on maximal medical therapy and 31% (N=141) had less limited coronary disease.

TABLE 4
Waiting times of patients referred for coronary artery bypass graft in 1994/1995 and 1998/1999 by priority and recommended waiting time

		1994/1995			1998/1999		
Priority	Recommended waiting time	Total (N)	Target (N)	Target (%)	Total (N)	Target (N)	Target (%)
Very urgent	<24 h	31	7	23	24	5	21
Urgent	<72 h	122	30	24	141	42	30
Semi-urgent	<2 weeks	87	56	64	68	33	49
Short wait	<6 weeks	98	49	50	59	42	71
Delayed wait	>6 weeks	53	40	75	201	71	35
	<6 months	391			493*		

**Of 578 patients referred, 61 were repeat cardiac catheterizations; they were excluded from this analysis. A further 24 were unassignable because they did not have angina. 'Target' refers to patients who received surgery within the recommended waiting time*

An assessment of all patients with critical coronary disease who were not repeat CAs suggested that CABG was necessary in 491 (95%) patients referred for CABG in 1998/1999. Thirty-eight of 491 patients were scored as needing PTCA, but coronary anatomy precluded PTCA, and CABG was undertaken instead. A further 91 patients needed CABG but were not referred. Of the latter group, 86% (N=78) were actually treated with PTCA. This could reflect new indications for PTCA and stenting determined after RAND criteria were developed (4,8). Thus, the referral rate from cardiology (N=517) was similar to the necessity rate identified by objective criteria (N=504).

Waiting times for CABG

Table 4 shows the waiting times according to priority and recommended waiting time. In 1998/1999, only 39% of patients received CABG within the recommended waiting time, compared with 47% in 1994/1995. The biggest deterioration in efficiency (proportion who received surgery within the recommended waiting time) occurred in those designated delayed wait priority.

Utilization data from 1998 to 2002

In 1999/2000, the annual growth in CA was 3.3%, but the growth in those referred for CABG was 6.0% (Table 5). This was partly influenced by inclusion of patients who had repeat CA while waiting for CABG and by a reduction in the rate of PTCA. The number of CABGs actually performed was less than the number referred and the wait list increased. In 2000/2001, for the first time the number of CABG performed exceeded the number referred and the wait list decreased. However, the number referred for CABG increased dramatically, by 14.2%, in the following year, substantially higher than the growth rate in CA.

In 1995, the annual number of CABGs recommended per year was 462, but this was not achieved until 1999/2000 (N=473). This was not related to inadequate funding but caused by the need to build a cardiovascular intensive care unit, and by problems in ensuring adequate numbers of perfusionists, anesthetists and cardiac surgeons. In the previous years, the number of CABGs performed was 375 in 1995/1996, 460 in 1997/1998 and 437 in 1998/1999. During this time, the number of new patients referred for CABG increased from 391 in 1994/1995 to 517 in 1998/1999, an increase of 8% per

TABLE 5
Coronary revascularization utilization data for 1998 to 2002

	1998/1999	1999/2000	2000/2001	2001/2002
Coronary catheterization +	2196	2269	2258	2389
Referred for CABG (%)	578 (26)	613 (27)	628 (28)	717 (30)
PTCA (%)	631 (29)	536 (24)	529 (23)	550 (23)
CABG done	437	473	641	626
CABG wait list	227	308	223	243
Annual growth in				
CA (%)	9.2*	3.3	–0.5	5.8
CABG (%)	12.0*	6.0	2.4	14.2
PTCA (%)	39.0*	–15.1	–1.3	4.0

**Derived from increase from 1994/1995. + Includes patients who had repeat coronary angiography (CA) while on the coronary artery bypass graft (CABG) wait list. PTCA Percutaneous transluminal coronary angioplasty*

year. This constant deficit between demand for CABG and actual supply of CABG increased the wait list to 308 in 1999/2000 (Table 5).

The proportion of patients referred for CABG in 1994/1995 was 24% of CAs performed, whereas in 2001/2002, it was 30%. Part of this increase was related to repeat CAs for patients already on the CABG wait list (2.8% of total CAs in 1998/1999).

DISCUSSION

The government of Newfoundland and Labrador agreed to fund CABG numbers according to need and the size of the waiting list, but the health care delivery system was slow in providing the capacity to meet the demand. This failure was exacerbated by the continued annual growth in the number of incident cases needing CABG. This growth was the result of greater use of CA and referral of patients with stable coronary syndromes than had occurred in 1994/1995. The disparity between supply and demand led to a longer waiting list and further deterioration in waiting times for CABG.

The present report demonstrates that the proportion of patients diagnosed with critical coronary artery disease, among those who had CA performed, increased from 68% in 1994/1995 to 74% in 1998/1999; the proportion of inappropriate CA was low (4%); the necessity rate in those referred for CABG was high (95%); and the proportion referred for CABG with limited disease (one- or two-vessel disease without involvement of the proximal left anterior descending artery) was low in 1994/1995 (10%) and in 1998/1999 (9%). This is compatible with the belief that growth in CABG utilization increased from a relatively low baseline rate and would not be expected to be associated with a large increase in unnecessary surgeries (3). These data confirm that clinical decision-making continued to be acceptable and that increased use of public funds was necessary to meet the needs of the community.

Despite the fact that the RAND methodology was published in 1993, and that indications for catheterization and revascularization changed in the mid 1990s, high levels of necessity and appropriateness were nonetheless observed in the 1998/1999 cohort.

From the patients' perspective, the deterioration in wait list times for CABG was probably a source of frustration, dissatisfaction with the health care system, morbidity and perhaps an increased risk of death (9). However, when compared with thousands of other patients living with coronary artery disease, such as those who had survived for six months after a myocardial infarction, they are at a similar or decreased risk of death (10,11).

From the doctors' perspective, the government's decision to fund the program according to the referral rate from cardiology was welcomed. The difference between the number of patients referred by cardiologists and the number projected by objective criteria was small. The government wants a reliable method to benchmark the numbers that they will need to fund, and will not interfere with clinical decision-making unless the disparity between objective need and demand widens.

From the provincial government's perspective, the continuing growth in the need for CABG, in a publicly funded health care system, induces substantial stress on the provincial budget, and raises questions concerning the capacity to fund such growth. Of particular concern to the payer is the unpredictable growth rate.

The volume of patients receiving catheterization and revascularization procedures have increased rapidly in other Canadian provinces since the mid 1990s, although rates are higher in Newfoundland. In Ontario, the rate of cardiac catheterization in 2000/2001 was 458 per 100,000 adults (12), whereas in Newfoundland it was 562 per 100,000 adults. During the same time period, the rate of percutaneous coronary interventions in Ontario was 120 per 100,000 versus 132 per 100,000 in Newfoundland (12). In Ontario, the rate of CABGs performed in 1999 was 104 per 100,000 adults (13), whereas it was higher (118 per 100,000) in Newfoundland. The change in target number of CABGs required in Newfoundland increased from 462 (115 per 100,000 adults) in 1995/1996 to 717 (178 per 100,000) in 2001/2002.

CONCLUSIONS

We conclude that the referral rate by cardiologists for CABG, which takes into account changes in clinical practice, is currently a reasonable way in which to plan the funding of the CABG program in Newfoundland. The increased growth in acceptable demand for CABG, induced by referrals with class I to III angina for more elective surgery, must be taken into account in predicting future benchmarks. However, changes in clinical practice, which may occur quickly and may be influenced by barriers to revascularization, will make these predictions difficult. The enormous increase in target number of CABGs required is stressful to a publicly funded health care delivery system, which has agreed to benchmark funding the number of CABGs based on need.

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