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UMI
A RANDOMIZED TRIAL OF THE ISCHEMIC HEART DISEASE
SHARED DECISION MAKING PROGRAM:
AN EVALUATION OF A DECISION AID.

by

Matthew William Morgan

A thesis submitted in conformity with the requirements for the degree of
Masters of Science in Clinical Epidemiology,
Department of Community Health,
University of Toronto.

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Abstract

A Randomized Trial of the Ischemic Heart Disease Shared Decision Making Program: An Evaluation of a Decision Aid.

Masters of Science in Clinical Epidemiology, Department of Community Health, University of Toronto, 1997.

Matthew William Morgan

This randomized trial evaluated the Ischemic Heart Disease Shared Decision Making Program (IHD SDP). The purpose was to determine if the IHD SDP, when compared to usual practice, improved patients' decision making.

One hundred and eighty patients completed the study. The SDP group had a mean satisfaction with decision making process score of 72 % compared to a mean of 70 % for the control group (p = 0.5). The SDP group had a mean knowledge score of 76 % compared to a mean of 62 % for the control group (p < 0.005) and chose to pursue revascularization 59 % of the time whereas 76 % of the control group chose revascularization (p=0.02).

We conclude that the IHD SDP, when compared to usual practice, did not increase patients' satisfaction but increased patient knowledge and may decrease revascularization.
Acknowledgments

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It became a reality because of the vision of my supervisor and teacher, Allan S. Detsky.

People instrumental in the success of this thesis included the other two members of my Thesis Committee: H. A. Llewellyn-Thomas and Donald Redelmeier; and the other co-investigators: Peter Gladstone, Raisa B. Deber, R.J. Cusimano and Keith O’Rourke.

Many others were instrumental in bringing this study to a conclusion ahead of schedule and under-budget, they included: Donna Cadeau for going above and beyond the call of duty by ensuring the cardiologists completed the referral forms and by making day to day enrollment so much fun; the cath lab nurses and cardiologists at TTH, Western division; the expert research assistance of Nancy Kraetschmer, Kevin Laupland, Matt Crystal and Angela Evelyn; the work of Niall Ferguson on the knowledge questionnaire: the efficient data entry of Nathaniel Chan; and Desiree Chanderbhan for her administration support.

I greatly appreciate the collaboration of Michael Barry, Annette O’Connor, Rasia Deber, Nancy Kraetschmer and Margaret Holmes-Rovner who allowed me to use their scales as our primary and secondary outcome measures.

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Chapter I: Introduction

Study Objectives

The primary objective of this study was to determine if the Ischemic Heart Disease Shared Decision Making Program (IHD SDP), when compared to usual patient-physician decision making, improved patients' satisfaction with the decision making process when facing a treatment decision about coronary revascularization.

Secondary objectives were to determine, at the time of treatment decision, the impact of the IHD SDP on patients':
1. knowledge on ischemic heart disease and treatment choices;
2. uncertainty with the decision making process;
3. initial treatment decision;
4. role in decision making;
5. satisfaction with the treatment decision made.

Primary Study Question

For patients with ischemic heart disease who are facing a treatment decision about elective coronary revascularization, does the IHD SDP, as compared to usual patient-physician decision making, increase patients' satisfaction with the decision making process?

Secondary Study Questions

Does the IHD SDP improve patients' knowledge deemed necessary to an informed treatment decision? Does the IHD SDP decrease patients' uncertainty around the treatment decision? Does the IHD SDP affect patients' initial treatment decision? Does
the IHD SDP affect patients' satisfaction with the decision made? Does the IHD SDP
affect patients' role in decision making?

**Scope of the problem**

Ischemic heart disease remains the leading cause of mortality and hospitalization in
Canadian adults over the age of 35.¹ Standard modes of therapy for ischemic heart
disease include medical therapy, coronary artery bypass surgery and angioplasty.
Utilization of bypass surgery and angioplasty has increased significantly in Canada over
the last decade.²,³ This increase in utilization of both forms of revascularization is
expected to increase as the population ages.³

A meta-analysis of the effectiveness of coronary artery bypass surgery compared to
medical therapy as the initial treatment choice for stable angina has been reported.⁴ This
overview of over 2600 patients revealed that the benefits of surgery with regards to
improving survival were greatest for those with extensive ischemic heart disease. Surgery
was also shown to be highly effective at relieving angina and decreasing the need for
antianginal medications but did not alter outcomes of myocardial infarction, left
ventricular function or return to gainful employment when compared to medical therapy.

The first randomized controlled trial (RCT) comparing angioplasty to medical
therapy showed that angioplasty was more effective at relieving symptoms in patients with
single vessel disease.⁵ Four RCTs comparing coronary artery bypass surgery to
angioplasty in patients with multivessel disease have been reported.⁶⁻⁹ Two of the studies
revealed that those treated with angioplasty were more likely to have persistent angina, to
require more antianginal medications and to require additional revascularization; however
there was no difference in mortality or myocardial infarction between the two groups.\textsuperscript{7,9} The other two studies reported similar outcomes, with the exception that those randomized to bypass surgery were more likely to have a procedure-related myocardial infarction.\textsuperscript{6,8} There have been no RCTs comparing all three treatment modalities (medical therapy, coronary artery bypass surgery and angioplasty). However, a large observational prospective cohort study of approximately 3000 patients in each of the three treatment groups followed for five years has been reported.\textsuperscript{10} The results, when left main coronary artery disease was excluded, showed a survival advantage for bypass surgery over medical therapy for patients with three vessel and severe two vessel disease. In patients with less severe disease, there was a relative trend towards increased survival for angioplasty over medical therapy. The authors suggested that the choice of treatment is a complex decision requiring consideration of many dimensions of outcome, including survival, functional status, symptom relief, quality of life and patient preference. Other experts have echoed these thoughts.\textsuperscript{7,9,11}

In summary, in cases such as left main disease and triple vessel disease with poor left ventricular function, there is strong evidence that coronary artery bypass surgery can result in a definite survival advantage.\textsuperscript{4} However, with less severe disease this survival advantage is uncertain, so the optimal choice of treatment is less clear. In such circumstances, the selection of treatment must be guided not only by possible survival advantages but also by the probability of symptom relief, impact on quality of life and patient preference.
Shared decision making

The philosophy of shared decision making is based on the premise that patients are able to judge the extent to which their disease and symptoms are interfering with their way of life, and they should therefore be active partners in the decision making process. Implicit in this philosophy is the recognition that the focus has shifted from physician centered care to patient centered care. Kassirer wrote that “physicians must set aside their image of themselves as making life-and-death decisions alone and undertake instead the less glamorous and more time consuming process of exploring optimal outcomes with the patient”. Patient participation and physician disclosure and communication of information is essential to this process.

Today, such a process is becoming increasingly dependent on the practice of evidence based medicine and the physician’s ability to effectively communicate that evidence to patients in a compassionate manner. The process also requires a recognition that patients differ both in the amount of information they desire and the role they wish to play in decision making.

As an example, in a study among women with breast cancer, a significant proportion of women were identified who desired more detailed information and a more active role in the decision making. However, a second group of women were identified that did not want detailed information and did not want to play active roles in the decision making. In another study, Deber proposed that shared decision making can be divided into two tasks: “problem solving” and “decision making”. Deber argues that patients do
not wish to play a major role in problem solving and usually do not have the expertise to do so but when provided with information, patients do wish and are capable of playing a major role in decision making.

Problem solving is equivalent to data gathering, the result of which leads to one correct conclusion. An example of problem solving would be concluding that a patient has significant coronary artery disease based on a history of worsening angina and the presence of significant left main coronary artery disease on angiogram. Decision making, on the other hand, is equivalent to weighing the risks and benefits of various options and making a decision with the highest expected utility for that decision maker. An example of decision making would be deciding to delay bypass surgery in the case described above until after the wedding of the patient's daughter.

Deber et al. provide evidence for this hypothesis from a survey of 300 patients undergoing coronary angiography. In this study patients overwhelmingly wanted the problem solving to be performed by or shared with the physician, but did not want to hand over decision making control to the physician.¹⁴

The respect of patient autonomy is implicit to the principle of shared decision making. Informed consent, as part of this principle, has become an essential component of the patient-physician relationship, however it is not equivalent to shared decision making. The simple act of authorizing a clinician to perform a procedure does very little to empower the patient in the decision making process. Studies have shown that informed consent procedures alone have not fully met patients information needs, are often poorly understood and do little to empower patients.¹⁷,¹⁸
The overall goal of shared decision making is to assist patients in the decision making process with the result being an effective decision. O'Connor defines an effective decision as one that is "informed, consistent with personal values and acted upon." Several indicators of effective decisions are improved information understanding or knowledge, decreased uncertainty about the decision, realistic expectations of outcomes, a commitment to the decision and greater overall satisfaction with the decision making process and decision made. \textsuperscript{19,20}

There are many obstacles to providing patients, who are facing treatment decisions, with the needed information that will allow them to make effective decisions. First, there must be a recognition that the patients' information needs are not being met. Second, a practical process must be in place to meet patients' information needs. Third, this process must be incorporated into the real and often time constrained world of clinical medicine. Fourth, the information must be presented in a way that the patient finds acceptable both in format and content. Fifth, the timing of information delivery must be appropriate. Sixth, there must be acceptance of the process by both the physicians and patients involved. Finally, the process must be flexible enough to manage the different information needs and roles in decision making that patients desire. In response to these obstacles, the need for decision support tools or decision aids in health care delivery is evident.

**Decision aids**

A decision aid can be defined as an "intellectual instrument in which data, information and knowledge related to a particular decision have been collected and
structured in a way that directly supports the cognitive processes used in arriving at a particular decision.” The need for decision aids is highlighted by a number of trends in society described by Llewellyn-Thomas as “… pressures from rising health care consumerism, increasingly complex therapeutic options, and concerns about the ethical and economic consequences of uninformed or inappropriate decision.” This need has resulted in the rapid development of a variety of patient decision aids using technologies that include decision boards, audiotape-booklets, linear videos and interactive videodiscs.

Decision aids are not equivalent to patient education programs as reviewed by Llewellyn-Thomas. Educational programs provide general information that is widely applicable to a patient population. Decision aids provide specific detailed information, tailored to each patient’s characteristics and focus on particular treatment choices. Decision aids describe the risks and benefits and consequences of each treatment option often expressed in terms of probabilities. They often involve the patient in exercises designed to clarify their values, understand trade-offs and promote realistic expectations of the treatment’s outcome. Decision aids are designed to do more than inform the patient but rather assist the patient in becoming an active participant in the decision making process.

Shared Decision Making Programs

The Ischemic Heart Disease Shared Decision-making Program (IHD SDP) is a decision aid that was developed as a collaboration between the Toronto group (Drs. Detsky and Deber, with funding from the Ontario Ministry of Health) and the Foundation
for Informed Medical Decision Making, Inc. (particularly Dr. A. Mulley, Massachusetts General Hospital and Dr. J. Wennberg, Dartmouth University).


The purpose of SDPs is to provide patients, with physician guidance, with clear, accurate and objective information about treatment options so that patients can be more active partners in the decision making process.22 The IHD SDP presents information about the possible risks and benefits associated with the three treatment alternatives for stable angina: medical therapy, bypass surgery and angioplasty. The probability estimates of these risks and benefits are tailored to each patient's particular medical and personal circumstances including age, gender, severity of symptoms, left ventricular function and coronary artery anatomy. This provides a standardized, interactive, personalized program. The content of IHD SDP is based on outcomes research from the Duke data bases, Agency for Health Care Policy and Research and its support of Patient Outcomes Research Teams. Information is also derived from an extensive review and analysis of the
published literature, as well as interviews with clinical investigators, experts in the field and focus groups with patients (which included Toronto focus groups).

IHD SDP incorporates filmed segments wherein patients who have already faced the decision and are presently living with the resulting outcome share their experience. Computer graphics are also incorporated to give patients a further understanding about their medical condition and probabilities of survival for different treatment options.

IHD SDP is interactive in two ways. First, there are patient-specific presentations of outcome probabilities based on individual patient risk factors and clinical variables such as left ventricular function and coronary artery anatomy. Second, it allows patients to view additional material of their choosing in the "Learn More" section, such as healthy lifestyle changes. Thus, patients are provided with a core amount of information that is specific to their clinical state and are given an opportunity to view additional information that they consider important.

The physician remains an integral part of the decision making process. IHD SDP is not designed to supplant the physician but rather enhance the patient-physician relationship. Physicians receive a summary of the patient's interaction with IHD SDP outlining the important points covered and the patient's treatment preferences.

Previous Studies of SDPs

Preliminary descriptive reports of an earlier developed shared decision making program on benign prostatic hyperplasia (BPH) revealed that the decision aid is a feasible approach both for communicating relevant information to patients and eliciting patient treatment preferences. Furthermore, patients responded favourably and
enthusiastically to the BPH SDP in these reports. A recent report showed that patients rated the BPH shared decision making program very positively and made treatment decisions consistent with their assessed preferences. A previous study revealed that prostatectomy rates declined and watchful waiting increased for a cohort of patients exposed to the BPH SDP when compared to historical data.

The only randomized controlled trial of an SDP was recently completed by Barry et al. using the BPH SDP. The objective of their study was to evaluate the impact of the BPH SDP on treatment decisions. The results were based on 104 men randomized to view the SDP and 123 controls. Patients were followed for one year and when compared to controls, SDP patients had significantly higher knowledge scores, higher satisfaction with the decision making process scores and higher general health perception and physical functioning scores. However, the SDP and control groups did not differ on the distribution of treatment decisions, satisfaction with actual decision made, BPH severity, social functioning and autonomy preference (see Table 1). The authors concluded “that the Shared Decision-making Program improves the quality of treatment decisions for BPH along several dimensions: decisions are better informed, patients are more satisfied with the decision-making process, and overall health is improved in terms of both general health perceptions and physical functioning.”

There has been one published observational study of the IHD SDP. In this pilot study, 60 patients who had recently been diagnosed with significant coronary artery disease viewed the IHD SDP. Patients completed questionnaires pre and post viewing. The results showed that the cohort of patients rated the SDP as more helpful than all other decision aids except the physician, increased confidence in the treatment choice and
decreased confidence in alternative treatments.
Table 1: Summary of the BPH SDP RCT

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>SDP Group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 123</td>
<td>N = 104</td>
<td></td>
</tr>
<tr>
<td>Mean age (SD)</td>
<td>66 (9)</td>
<td>66 (8)</td>
<td></td>
</tr>
<tr>
<td>Mean general health score (SD)</td>
<td>71 % (18)</td>
<td>67 % (19)</td>
<td></td>
</tr>
<tr>
<td>Mean physical function score (SD)</td>
<td>83 % (19)</td>
<td>82 % (20)</td>
<td></td>
</tr>
<tr>
<td>Mean social function score (SD)</td>
<td>92 % (16)</td>
<td>91 % (16)</td>
<td></td>
</tr>
<tr>
<td>Mean SwDMP score (SE)</td>
<td>71 % (1.7)</td>
<td>76 % (1.6)</td>
<td>0.03</td>
</tr>
<tr>
<td>Mean knowledge score</td>
<td>54 %</td>
<td>75 %</td>
<td>0.001</td>
</tr>
<tr>
<td>% Surgical treatment</td>
<td>13 %</td>
<td>8 %</td>
<td>0.3</td>
</tr>
</tbody>
</table>
Conceptual Framework

The increased use of decision has not been met by an equal rise in the evaluation of decision aids using appropriate instruments and outcomes.¹⁹,²⁰ O’Connor argues that decision aids should decrease patient uncertainty about the course of action to take and result in more effective decisions.¹⁹ Building on this conceptual framework, it can be argued, that decision aids should improve other indicators of effective decision making such as knowledge, expectations, commitment to the decision and satisfaction with the decision making process and decision made and ultimately improve the quality of care. To date, there have been very few prospective studies published that systematically evaluate the impact of decision aids in clinical practice. Evaluation of decision aids should therefore measure outcomes that are important indicators of effective decision making and the quality of care.

One such measure is patient satisfaction, which can be defined as a multidimensional measurement that subjectively measures a patient’s expectations and perceptions of a health care experience.³⁰ It directly measures what a patient thinks, and reflects whether his or her needs have been met. It provides a valuable measure of the effectiveness of decision making and the quality of care from the patient’s perspective.

Patient satisfaction as a measurement of effective decision making and quality of care is a relatively new area of research. In a review by Cleary and McNeil they suggest that no consensus exists on the role of satisfaction in these assessments.³¹ However, they review the research supporting its importance which shows that patient experiences that result in more “personal” care are associated with higher levels of patient satisfaction and
improved quality of care. Specifically patient satisfaction has been shown to correlate with patient characteristics, attitudes and expectations, the provision of information, recognition of patient needs, improved patient-physician communication and greater patient involvement.\textsuperscript{31}

Other research in patient satisfaction has shown that patients satisfied with medical care are more likely to remain with physicians, keep appointments, comply with treatment and refer others.\textsuperscript{32} Another study demonstrated that improved information giving by physicians was associated with improved patient satisfaction and compliance with treatment.\textsuperscript{33} The focus of patient satisfaction in decision making is the patient not the physician, which is congruent with shared decision making.

Decision aids should increase patient participation in the decision making, enhance information giving, increase patient autonomy, lead to more effective decision, improve patient satisfaction with the decision making process and ultimately the quality of care. We argue that patient satisfaction with the decision making process represents a global indicator of effective decision making. The primary goal of the IHD SDP is to assist patients in becoming more effective partners in the decision making process. In order to evaluate this goal, patient satisfaction with the decision making process at the time of treatment decision was measured and served as the primary outcome of this trial.

Three other indicators of effective decision making were also measured, information understanding or knowledge, uncertainty about the decision and satisfaction with the treatment decision made.
Patient knowledge of the disease, treatment options and the associated risks and benefits is an essential element of informed consent and the decision making process. A meta-analysis has shown that disclosure of information was significantly associated with patient satisfaction.\textsuperscript{33} Decision aids have been shown to increase information understanding in a variety of clinical settings.\textsuperscript{23-25,29} The IHD SDP is designed to provide patients with knowledge important in the decision making process. Its impact on this indicator of effective decision making was evaluated in this trial.

Patient uncertainty may translate into decisional conflict which is defined by O'Connor as "a state of uncertainty about the course of action to take".\textsuperscript{19} The lack of information about alternatives and their consequences has been hypothesized to contribute to uncertainty. In one study, patients who felt uninformed had greater difficulty making decisions.\textsuperscript{34} Additional factors contributing to decisional conflict include: unclear values, skill deficits in implementing decisions, emotional distress and perceived pressure from others.\textsuperscript{19}

The IHD SDP has the potential to reduce decisional uncertainty in several ways. First, it provides needed information specific to the patient. Second, it can assist in value clarification by detailing the risks and benefits of the treatment options. Third, it can assist patients in carrying through with the decision by presenting interviews with patients who are living with the consequences of their choice. Fourth, it can decrease the emotional distress experienced by enabling patients to gain control over the situation. Finally, it can provide an opportunity for family members and others to view the decision from the patient's perspective, allowing them to provide constructive feedback instead of unwanted
pressure. The impact of the IHD SDP on decisional conflict as an indicator of effective
decision making was evaluated in this trial.

Patient satisfaction with the actual decision is an important outcome measure for
interventions designed to support patients in explicit decision making. In a recent
observational pilot study of the IHD SDP it was found that after viewing the SDP,
patients reported increased confidence in the treatment decision and decreased confidence
in alternative options. In a recent validation study of a new satisfaction with decision
scale, Holmes-Rovner et al., showed that satisfaction with the decision correlated with
lower levels of decisional conflict and higher confidence in the decision The impact of
the IHD SDP on satisfaction with the treatment decision as an indicator of effective
decision making was evaluated in this trial.

The initial treatment decision is an important outcome of any decision making
process. Studies of the shared decision making program on benign prostatic hyperplasia
(BPH) have shown a trend in treatment decisions away from surgery and towards watchful
waiting in some patients. However, in a recent randomized controlled trial that
evaluated the BPH shared decision making program no statistical difference in initial
treatment decision was seen. In both the control and SDP groups the majority chose
watchful waiting, 87 % and 92 % respectively. The impact of the IHD SDP on the initial
treatment decision was evaluated in this trial.

As stated previously, recognition of the role patients play in decision making is
important to the philosophy of shared decision making. Deber argues that patients are
unwilling to delegate decision making entirely to physicians and would rather participate in
decisions that affect their lives. The aim of decision aids such as the IHD SDP is to assist patients in achieving this goal. It can therefore be argued that such decision aids should increase patients' role in decision making. Deber has shown that patients are unwilling to delegate decision making entirely to physicians and would rather participate in decisions that affect their lives. The impact of the IHD SDP on patients' role in decision making was evaluated in this trial.

The timing of all outcomes measures and study design is depicted in Figure 1.
Enrolled following angiogram
Baseline measures

Decision outcomes:
SwDMP
Knowledge
DCS
Treatment chosen
SWD
Role in decision

Figure 1  Study Design
Chapter II: Research Design and Methods

This study was a randomized, controlled clinical trial. The Toronto Hospital (TTH) was chosen as the study site. TTH is a University of Toronto teaching hospital at which over 4,000 coronary angiograms, 1,400 coronary artery bypass operations and 1,100 angioplasties are performed each year.

The rationale for choosing the RCT as the study design was that the IHD SDP is an expensive new technology, the value of which has not been proven. It can be argued that all new technologies before being widely accepted and used in clinical practice should be rigorously evaluated. The RCT has become the gold standard, when feasible, for such evaluations. Formal analysis of patient-physician encounters with audiotapes was considered impractical because of the intrusiveness and expense. Randomization of individual physicians was also considered in which all patients of one physician would be randomized to either the intervention or control group and analyzed as a unit. However to achieve sufficient power a multi-centered approach would have been required which would have added considerably to the expense and complexity of the study.

Target population

The target population consisted of symptomatic stable angina patients who had recent angiographic evidence of coronary artery disease amenable to elective revascularization (bypass surgery and/or angioplasty). Patients were considering revascularization for the first time and were eligible for at least two of the three treatment options: medical therapy, bypass surgery and/or angioplasty.
This population of patients was chosen for several reasons. First, these patients were facing a treatment decision in which there was a "gray zone" of uncertainty about the optimal treatment decision. As a result the patients and physicians were presented with a shared decision making scenario suitable for the evaluation of a decision aid. Second, ischemic heart disease is prevalent in our society and is a leading cause of morbidity and mortality. Third, the IHD SDP meets the definition of a decision aid and has been shown to assist in decision making in a pilot study. Fourth, these patients were considered elective candidates for revascularization, as a result the impact of this study on the usual course of decision making was judged to be minimal. Finally, first time decision makers were chosen since they have the greatest potential to benefit from the decision aid. Patients who have faced the treatment decision before are likely to be more knowledgeable and require less new information than first time decision makers. Any observed impact of the decision aid in shared decision making is likely to be greater and therefore more easily identified with first time decision makers.

Ethics

Since this randomized controlled trial examined a decision aid developed to inform patients about their medical condition and treatment choices, a fundamental element of informed consent, the risks associated with this study were thought to be minimal. Ethical approval of this study was obtained from The Toronto Hospital Ethical Review Committee (Appendix A).

All data was obtained from self-administered questionnaires, telephone interviews and consultation with the referring physicians. During the course of this trial all enrolled
patients continued to receive medical care as deemed appropriate by their physicians.

Withdrawal from the study by patients had no impact on patient care or ongoing professional contact with the investigators or TTH. The research team had access to the patients' names, addresses and telephone numbers in order to arrange appointments and follow-up. All data forms were coded with study ID numbers only. Linkage of names and study numbers were securely maintained by the study team. No patients were or will be identified in presentations or publications. A summary of results will be provided to all interested participants.

**Patient recruitment**

Ambulatory patients undergoing elective coronary angiography were recruited from TTH, Western Division Coronary Angiography Department. An eligibility criteria checklist was completed at the time of angiography, by the attending cardiologist, for each patient undergoing coronary angiography (Appendix B). Patients deemed eligible were approached post angiography, in the day patient bed unit before hospital discharge, by myself and/or a research assistant. After informed consent to participate in this study was obtained, consenting patients were randomized. A log of patients who accepted and declined enrollment was compiled and reasons for declining enrollment were requested and recorded.

**Patient eligibility**

The following inclusion criteria were utilized. All patients had to be older than 19 years of age with a diagnosis of ischemic heart disease, defined as >50% stenosis of at least one coronary artery. Patients also had to have angiographic evidence of coronary
artery disease amenable to elective revascularization (bypass surgery and/or angioplasty), as deemed by the attending cardiologist, in addition to the option of ongoing medical therapy. The patient’s left ventricular function had to be known and was provided by the attending cardiologist. Finally, a comprehension of English was required since only an English version of the SDP was available.

Patients were excluded if they were deemed by the attending cardiologist to have unstable angina pectoris, defined as: angina occurring at rest; accelerated angina or new onset angina. Furthermore, patients were excluded if they had significant left main coronary artery disease (> 50%) requiring urgent revascularization or valvular disease requiring valve replacement. Patients were also excluded if they had previous bypass surgery or coronary angioplasty or an immediate post-angiogram complication resulting in an unexpected hospital stay. Finally, patients were excluded if only one of three treatment options (bypass surgery, angioplasty and/or medical therapy) was deemed appropriate by the referring cardiologist. The inclusion and exclusion criteria were incorporated into the patient checklist (Appendix B).

**Stratification and randomization**

Since not all patients were eligible for angioplasty it was necessary to stratify patients into the following two groups:

1. bypass or medical therapy candidates (i.e. ineligible for angioplasty because of coronary anatomy);

2. bypass or angioplasty or medical therapy candidates.
The reason for this was to simply ensure balance in terms of the number of patients randomized to the SDP and control groups. For the statistical analysis and reported results, all patients randomized to the control groups were pooled as were those randomized to the SDP groups, as depicted in Figure 2. A third group of angioplasty or medical therapy patients was not required since all patients consenting to angioplasty were also informed about the possibility of emergency bypass surgery in the event of angioplasty complications.

Patients in each group were randomized to either the IHD SDP or control arm. Only the statistician was privy to the two randomization schedules and blocking factor used. All randomization enrollment was performed by telephone at which time the patient was assigned to either the control or intervention group.
Figure 2: Randomization and Stratification

- Eligible Pts: 279
  - 39 refusals
  - Enrolled Pts: 240
    - 60 drop-outs

- SAM: 110
  - Control: 37
  - IHD SDP: 33

- SM: 70
  - Control: 94
  - IHD SDP: 57

- IHD SDP: 53
Blinding

Due to the nature of the IHD SDP intervention neither the investigators nor the patients were blinded to the intervention.

The control arm

Patients randomized to usual patient-physician decision making care did not receive any additional educational material from the study investigators. The extent and nature of further decision making was left to the discretion of the patient and physicians directly involved with the patient's care.

The rationale for this, was to allow for a fair and realistic comparison of the IHD SDP to the present practice of decision making. Since this varies from physician to physician, we elected not to provide control patients with any additional educational material. The extent and nature of further decision making was left to the discretion of the patient and physician(s) directly involved with the patient's care. A fair and realistic comparison of the IHD SDP to the present practice of decision making is an important first step in the evaluation of this decision aid. Modification of the decision making process by providing all control patients with additional educational material would have defeated the purpose of the trial.

At the time of randomization, control patients were given the baseline questionnaire which was completed and returned by mail (Appendix C). At the time of treatment decision patients completed the decision questionnaire which was also returned by mail (Appendix E). Telephone follow-up was completed as needed.
The intervention arm

At the time of randomization, patients were given a written baseline questionnaire to be completed and returned by mail (Appendix C). Patients randomized to the intervention arm also received a brochure about the IHD SDP. The brochure contained educational information about the treatment choices for ischemic heart disease. These patients were given an appointment to view the IHD SDP within four weeks after angiography. The total time commitment involved for this session was sixty to ninety minutes. After viewing the IHD SDP, patients received a written summary of the main learning points, including the treatment options and the risks and benefits of those treatments. A physician copy of this written summary was also provided and intended for use at subsequent patient-physician decision making sessions (Appendix D).

At the time of treatment decision, patients completed a decision questionnaire which was also returned by mail (Appendix E). Telephone follow-up was completed as needed.

Baseline patient measures

The following baseline characteristics were obtained from the patient after randomization using a self-administered written questionnaire that was returned by mail: age, gender, educational level, annual household income, general health state (SF 36 General Health sub-scale\textsuperscript{36}) and preferred role in medical decision making (Problem Solving-Decision Making Scale\textsuperscript{14}) (Appendix C). The following baseline characteristics were obtained from the attending cardiologist who performed the angiogram, using a self
administered written baseline form: number of diseased coronary arteries, angina severity (Canadian Cardiovascular Society Classification for Angina Pectoris), left ventricular function and presence of comorbidities (Appendix B).

Outcome patient measures

Patient satisfaction with the decision making process

The decision satisfaction inventory (DSI) was developed by Barry et al. to assess patient satisfaction in decision making. This inventory is an eighteen item category rating scale with three sub-scales: overall satisfaction with medical care, satisfaction with the decision making process, and satisfaction with the decision made. Barry et al. evaluated the DSI in a randomized controlled trial of the shared decision making process for patients with benign prostatic hyperplasia. They found that the twelve item decision making process sub-scale (SwDMP) had a high Cronbach’s alpha of 0.95 and correlated with patients’ total scores for overall satisfaction with health care that were obtained on a scale previously developed and validated as part of the Health Insurance Experiment.

The results of the Barry et al. RCT revealed that BPH SDP patients had a mean score of 76% compared to a mean score of 71% for controls on the measure of satisfaction with the decision making process. This represented a statistically significant difference in satisfaction scores for the decision making process (p=0.03). The SwDMP sub-scale is scored by summing the responses after re-coding, with higher scores indicating greater satisfaction. The score is then normalized from 0 to 100% (Appendix E).
In this RCT we used the DSI SwDMP sub-scale at the time of treatment decision as our primary outcome.

**Patient knowledge**

We developed a twenty true/false item set to assess essential knowledge deemed necessary for an informed treatment decision. This item set was reduced to 15 for patients who were not eligible for angioplasty. The clinical judgment of an expert panel consisting of two general internists, a cardiologist, a cardiovascular surgeon and a bioethicist was used along with explicated Delphi technique to develop the item set. Correct responses were scored +1 and unsure and incorrect responses were scored 0. The total number of correct responses were summed and converted to score ranging from 0 to 100%, with higher scores indicating greater knowledge (Appendix E).

The criterion validity of this scale was assessed by measuring the improvement in scores on a cohort of 34 newly diagnosed ischemic heart disease patients, not enrolled in this study, before and after viewing a VHS video version of the IHD SDP. The patients had a mean score of 60% before viewing and 84% after viewing the SDP (p<0.005).

In this RCT, we used our knowledge scale to test patient knowledge at the time of the treatment decision.

**Patient uncertainty in decision making**

*The O'Connor Decisional Conflict Scale* (DCS) is a 16 item, five point category rating scale designed to elicit patient uncertainty in medical decision making, the factors contributing to uncertainty and perceived effective decision making.\(^9\) Scores are summed and divided by the number of items (scores of some items reversed) resulting in a score of
1 to 5, with higher scores indicating greater decisional conflict (Appendix E). The DCS was evaluated with 909 patients deciding about influenza immunizations and breast cancer screening. The test-retest reliability coefficient was 0.81 and internal consistency coefficients ranged from 0.78 to 0.92. The DCS discriminated between those who had strong intentions to either accept or decline treatment and those who were uncertain or delayed their decision, \( p < 0.0002\).

In this RCT, we used the DCS to measure patient uncertainty at the time of the treatment decision.

**Satisfaction with the decision made (SWD)**

The Satisfaction with Decision scale (SWD) measures satisfaction with health care decisions. It is a six item category rating scale. Scores are summed and divided by the number of items, resulting in a score of 1 to 5, with higher scores indicating greater decisional satisfaction (Appendix E). It was evaluated with women considering post-menopausal hormone-replacement therapy and showed excellent reliability, Cronbach’s alpha of 0.86. When compared to other scales measuring satisfaction it correlated most highly with decisional confidence, Cronbach’s alpha of 0.64.

In this RCT, we used the SWD to measure patient satisfaction with the decision at the time of the treatment decision.

**Treatment decision**

The impact of the IHD SDP on initial treatment choice was assessed at the time of treatment decision by asking patients what decision they had chosen using a single item scale at the time of treatment decision (Appendix E).
Role in decision making

In order to determine if the IHD SDP had an impact on patients' role in decision making, patients were asked to indicate who made the treatment decision, the patient, the physician or both. A single item 5 point category rating scale was used (Appendix E).

Data collection and management

Data collection occurred at the time of randomization and at the time of treatment decision. Data were primarily collected by mail however telephone follow-up was utilized to gather missing data. Double data entry was performed for all data and error rates were checked.

Sample size calculation

Calculation of sample size was based on work by Cohen\textsuperscript{19}, using the principle of effect size (d) defined as: \[
\frac{m_{IHD SDP} - m_{Usual}}{sd}
\]

where \( m \) is the mean score of the primary outcome, satisfaction with the decision making process, in the intervention group (IHD SDP) and control group (Usual) and where \( sd \) is the standard deviation of the scale used to measure the primary outcome.

We wished to detect an effect size of 0.5, considered by Cohen to be a medium effect size. This required \( m_{IHD SDP} - m_{Usual} = 0.5 \, sd \). Assuming independent samples drawn from equally varying populations, a sample size of 84 per group was required to obtain 90\% power to detect a difference in the primary outcome on the magnitude of one half a standard deviation between groups, with a 5\% risk of a type 1 error, two tailed.
Statistical analysis

For the statistical analysis the results from all patients randomized to the control groups were pooled, as were the results of all patients randomized to the SDP groups. Statistical tests were used to compare the two groups as described below.

The primary outcome was a single score, SwDMP. This twelve item category rating ordinal scale was summated and normalized, providing a range of scores from 0 to 100% (Appendix E). Nonparametric and parametric statistics were used to analyze this outcome. Both Wilcoxon rank sum tests and t-test statistics gave similar results. A difference in the group means of this score at the time of treatment decision was determined using the standard two sample t-tests.48

The outcomes of uncertainty with the decision making process (DCS) and satisfaction with the decision (SWD scale) were analyzed in a manner similar to the primary outcome measure. Statistical analysis with Wilcoxon rank sum tests and t-test statistics gave similar results.

The knowledge scale was summed and normalized to provide a score that ranged from 0 to 100%. This scale behaved similarly using Wilcoxon rank sum tests and t-test statistics.

The outcome of initial treatment decision was grouped as either ongoing medical therapy or revascularization, which included bypass surgery and angioplasty. This was reported as a simple percent of the total. For this categorical variable, a chi-square test for association was performed.
The outcome of role in decision making was evaluated as a categorical variable, a chi-square test for association was performed.

Baseline categorical and continuous variables were analyzed using the same statistically tests as described for the outcome measures.

In order to adjust for multiple comparisons, given there were 5 secondary outcomes, the Bonferroni test was performed. The observed significance level for the original comparison was changed to $p = 0.01$ ($0.05 / 5$) in order for the difference to be significant at the 0.05 significance value.
Chapter III: Results

Patient Accrual and Follow-up

Patient enrollment began August 22, 1995 and was completed June 27, 1996. Of the 279 eligible patients 240 consented and were enrolled in the study, an 86 % entrance rate. The reasons given for non-consent were not specific and included inconvenience and lack of interest.

Of the 240 consenting patients, 120 were randomized to the control arm and 120 to the SDP arm. In total, 60 of the 240 patients enrolled did not complete the study, representing a 25 % drop-out rate. Of these, 34 were enrolled in the SDP group and 26 in the control group. Baseline demographics were obtained for 27 of these 60 patients (see Table 2). Reasons obtained for dropping-out of the study included: required urgent revascularization (9), did not meet inclusion criteria (3), enrolled in another study (2), moved to another province (3), incorrect randomization (1), unknown / refused post randomization (42).

The results are therefore based on data from 180 patients ( 86 SDP, 94 control) who completed the trial, representing 75 % complete follow-up.

Baseline Characteristics

The baseline characteristics for 27 of the 60 drop-outs and the 180 patients who completed the study are listed in Table 2. Differences between the two groups existed. Specifically the drop-out group reported lower incomes, lower general health and physical functioning scores, and higher bodily pain scores (p ≤ 0.05). The baseline characteristics
for the 94 control patients and the 86 SDP patients who completed the study are listed in Table 3. No significant statistical differences were found between the control and SDP group.
Table 2: Comparison of baseline characteristics of those who dropped-out and those who completed the study

<table>
<thead>
<tr>
<th></th>
<th>Dropouts (N=27)</th>
<th>Complete (N=180)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>61 (10)</td>
<td>60 (10)</td>
<td>0.5</td>
</tr>
<tr>
<td>Percent male</td>
<td>81 %</td>
<td>89 %</td>
<td>0.3</td>
</tr>
<tr>
<td>Percent married</td>
<td>85 %</td>
<td>88 %</td>
<td>1</td>
</tr>
<tr>
<td>Educational level</td>
<td></td>
<td></td>
<td>0.8</td>
</tr>
<tr>
<td>less than high school</td>
<td>35 %</td>
<td>30 %</td>
<td></td>
</tr>
<tr>
<td>high school graduate</td>
<td>15 %</td>
<td>20 %</td>
<td></td>
</tr>
<tr>
<td>some college</td>
<td>11 %</td>
<td>16 %</td>
<td></td>
</tr>
<tr>
<td>college graduate</td>
<td>39 %</td>
<td>34 %</td>
<td></td>
</tr>
<tr>
<td>Income level</td>
<td></td>
<td></td>
<td>0.05</td>
</tr>
<tr>
<td>less than $40 000</td>
<td>59 %</td>
<td>39 %</td>
<td></td>
</tr>
<tr>
<td>$40 000 - $60 000</td>
<td>7 %</td>
<td>17 %</td>
<td></td>
</tr>
<tr>
<td>more than $ 60 000</td>
<td>19 %</td>
<td>37 %</td>
<td></td>
</tr>
<tr>
<td>unknown</td>
<td>15 %</td>
<td>7 %</td>
<td></td>
</tr>
<tr>
<td>CCVS Angina scale</td>
<td></td>
<td></td>
<td>0.4</td>
</tr>
<tr>
<td>class I</td>
<td>11 %</td>
<td>22 %</td>
<td></td>
</tr>
<tr>
<td>class II</td>
<td>44 %</td>
<td>45 %</td>
<td></td>
</tr>
<tr>
<td>class III</td>
<td>44 %</td>
<td>31 %</td>
<td></td>
</tr>
<tr>
<td>class IV</td>
<td>0 %</td>
<td>2 %</td>
<td></td>
</tr>
<tr>
<td># of diseased arteries</td>
<td></td>
<td></td>
<td>0.8</td>
</tr>
<tr>
<td>one</td>
<td>15 %</td>
<td>21 %</td>
<td></td>
</tr>
<tr>
<td>two</td>
<td>22 %</td>
<td>23 %</td>
<td></td>
</tr>
<tr>
<td>three or more</td>
<td>63 %</td>
<td>56 %</td>
<td></td>
</tr>
<tr>
<td>LV function</td>
<td></td>
<td></td>
<td>0.9</td>
</tr>
<tr>
<td>grade I</td>
<td>59 %</td>
<td>55 %</td>
<td></td>
</tr>
<tr>
<td>grade II</td>
<td>26 %</td>
<td>34 %</td>
<td></td>
</tr>
<tr>
<td>grade III</td>
<td>11 %</td>
<td>8 %</td>
<td></td>
</tr>
<tr>
<td>grade IV</td>
<td>4 %</td>
<td>2 %</td>
<td></td>
</tr>
<tr>
<td>Comorbidities present (SD)</td>
<td>22 %</td>
<td>21 %</td>
<td>0.9</td>
</tr>
<tr>
<td>Mean general health score (SD)</td>
<td>46 % (26)</td>
<td>57 % (19)</td>
<td>0.007</td>
</tr>
<tr>
<td>Mean physical functioning score (SD)</td>
<td>50 % (29)</td>
<td>60 % (25)</td>
<td>0.05</td>
</tr>
<tr>
<td>Mean social functioning score (SD)</td>
<td>59 % (33)</td>
<td>67 % (27)</td>
<td>0.1</td>
</tr>
<tr>
<td>Bodily pain score (SD)</td>
<td>52 % (28)</td>
<td>66 % (25)</td>
<td>0.008</td>
</tr>
</tbody>
</table>
Table 3: Comparison of baseline characteristics of SDP group and controls

<table>
<thead>
<tr>
<th></th>
<th>Control Group (N=94)</th>
<th>SDP Group (N=86)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>60 (9.6)</td>
<td>60 (9.6)</td>
<td>0.9</td>
</tr>
<tr>
<td>Percent male</td>
<td>87 %</td>
<td>91 %</td>
<td>0.9</td>
</tr>
<tr>
<td>Percent married</td>
<td>88 %</td>
<td>87 %</td>
<td>1</td>
</tr>
<tr>
<td>Educational level</td>
<td></td>
<td></td>
<td>0.7</td>
</tr>
<tr>
<td>less than high school</td>
<td>28 %</td>
<td>33 %</td>
<td></td>
</tr>
<tr>
<td>high school graduate</td>
<td>23 %</td>
<td>16 %</td>
<td></td>
</tr>
<tr>
<td>some college</td>
<td>16 %</td>
<td>16 %</td>
<td></td>
</tr>
<tr>
<td>college graduate</td>
<td>33 %</td>
<td>35 %</td>
<td></td>
</tr>
<tr>
<td>Income level</td>
<td></td>
<td></td>
<td>0.4</td>
</tr>
<tr>
<td>less than $40 000</td>
<td>39 %</td>
<td>40 %</td>
<td></td>
</tr>
<tr>
<td>$40 000 - $60 000</td>
<td>13 %</td>
<td>21 %</td>
<td></td>
</tr>
<tr>
<td>more than $60 000</td>
<td>38 %</td>
<td>35 %</td>
<td></td>
</tr>
<tr>
<td>unknown</td>
<td>10 %</td>
<td>5 %</td>
<td></td>
</tr>
<tr>
<td>CCVS Angina scale</td>
<td></td>
<td></td>
<td>0.8</td>
</tr>
<tr>
<td>class I</td>
<td>20 %</td>
<td>24 %</td>
<td></td>
</tr>
<tr>
<td>class II</td>
<td>44 %</td>
<td>47 %</td>
<td></td>
</tr>
<tr>
<td>class III</td>
<td>33 %</td>
<td>28 %</td>
<td></td>
</tr>
<tr>
<td>class IV</td>
<td>2 %</td>
<td>1 %</td>
<td></td>
</tr>
<tr>
<td># of diseased arteries</td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>one</td>
<td>25 %</td>
<td>16 %</td>
<td></td>
</tr>
<tr>
<td>two</td>
<td>27 %</td>
<td>19 %</td>
<td></td>
</tr>
<tr>
<td>three or more</td>
<td>48 %</td>
<td>64 %</td>
<td></td>
</tr>
<tr>
<td>LV function</td>
<td></td>
<td></td>
<td>0.3</td>
</tr>
<tr>
<td>grade I</td>
<td>50 %</td>
<td>61 %</td>
<td></td>
</tr>
<tr>
<td>grade II</td>
<td>40 %</td>
<td>28 %</td>
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</tr>
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<td>grade III</td>
<td>7 %</td>
<td>9 %</td>
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</tr>
<tr>
<td>grade IV</td>
<td>3 %</td>
<td>1 %</td>
<td></td>
</tr>
<tr>
<td>comorbidities present (SD)</td>
<td>17 %</td>
<td>24 %</td>
<td>0.3</td>
</tr>
<tr>
<td>Mean general health score (SD)</td>
<td>58 % (19)</td>
<td>57 % (20)</td>
<td>0.8</td>
</tr>
<tr>
<td>Mean physical health score (SD)</td>
<td>61 % (25)</td>
<td>59 % (25)</td>
<td>0.6</td>
</tr>
<tr>
<td>Mean social health score (SD)</td>
<td>65 % (27)</td>
<td>70 % (27)</td>
<td>0.3</td>
</tr>
<tr>
<td>Bodily pain score (SD)</td>
<td>64 % (24)</td>
<td>68 % (25)</td>
<td>0.3</td>
</tr>
</tbody>
</table>
Primary outcome

Satisfaction with the decision making process (SwDMP)

At the time of decision making, the SDP group had a mean satisfaction with decision making process score of 72% compared to a mean of 70% for the control group, where higher scores indicate greater satisfaction. The observed increase of 2% was not statistically significant (p = 0.5). The 95% confidence intervals of this delta were -4%, +7% (see Table 4). Summary statistics for the distribution of this outcome in both groups are displayed in the boxplot depicted in Figure 3.
Table 4: Outcome Scores for the SDP group and Controls

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control Group N=94</th>
<th>SDP Group N=86</th>
<th>Δ</th>
<th>95% CI around Δ</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SwDMP</td>
<td>70 %</td>
<td>72 %</td>
<td>2 %</td>
<td>(+2 %, +7 %)</td>
<td>0.6</td>
<td>0.5</td>
</tr>
<tr>
<td>Knowledge</td>
<td>62 %</td>
<td>76 %</td>
<td>14%</td>
<td>(+8 %, +18 %)</td>
<td>5</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>DCS</td>
<td>2.1</td>
<td>2.1</td>
<td></td>
<td></td>
<td>-0.7</td>
<td>0.5</td>
</tr>
<tr>
<td>Treatment Decision</td>
<td>76 %</td>
<td>59 %</td>
<td>17 %</td>
<td>(+3 %, +30 %)</td>
<td>-2</td>
<td>0.02</td>
</tr>
<tr>
<td>Revasc.</td>
<td>24 %</td>
<td>41 %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SWD</td>
<td>4.1</td>
<td>4.2</td>
<td></td>
<td></td>
<td>-0.5</td>
<td>0.6</td>
</tr>
<tr>
<td>Patient Role</td>
<td>58 %</td>
<td>71 %</td>
<td></td>
<td></td>
<td></td>
<td>0.03</td>
</tr>
<tr>
<td>(shared)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 3: Boxplot of Distribution of Primary Outcome, SwDMP
Secondary outcomes

Knowledge

At the time of decision making, the SDP group had a mean knowledge score of 76% compared to a mean of 62% for the control group, where a higher score indicates greater knowledge deemed important in decision making. The observed increase of 14% was statistically significant \( p < 0.005 \). The 95% confidence intervals of this delta were +8%, +18% (see Table 4).

Decisional conflict

At the time of decision making, both the SDP group and control group had a mean decisional conflict score of 2.1, where a score of 1 indicates low decisional conflict and a score of 5 indicates high decisional conflict (see Table 4).

In 4 of the 5 sub-scales of the DCS, the mean scores between the groups did not differ, however in the "Information Needs" sub-scale, the SDP group score was lower, 1.8 compared to 2.1, respectively. This implies the IHD SDP group’s information needs were better met than the control group (see Table 5). Although statistically significant before adjusting for multiple comparisons \( p = 0.02 \) this significance was lost after the Bonferroni correction was applied.
Table 5: Decisional Conflict Scale and Sub-scales for the SDP group and Controls

<table>
<thead>
<tr>
<th></th>
<th>Control Group (N=94) mean score</th>
<th>SDP Group (N=86) mean score</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCS (overall)</td>
<td>2.1</td>
<td>2.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Sub-scales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncertainty</td>
<td>2.3</td>
<td>2.4</td>
<td>0.4</td>
</tr>
<tr>
<td>Information needs</td>
<td>2.1</td>
<td>1.8</td>
<td>0.02</td>
</tr>
<tr>
<td>Values</td>
<td>2.2</td>
<td>2.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Social support</td>
<td>2.3</td>
<td>2.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Perceived effectiveness</td>
<td>1.9</td>
<td>1.8</td>
<td>0.6</td>
</tr>
</tbody>
</table>
**Treatment decision**

At the time of decision making, 59% of the SDP group chose to pursue revascularization (either coronary artery bypass surgery or angioplasty) whereas 76% of the control group chose revascularization. Stated another way, 41% of the SDP group chose medical therapy or “watchful waiting” whereas only 24% of the control group chose this option (see Table 4). The statistical significant of this result (p=0.02) was lost after the Bonferroni correction was applied.

**Role in decision making**

When asked to indicate who made the treatment decision, 29% of the SDP group indicated that the decision was made “mostly” or “only” by the doctors, whereas 42% of the control group indicated this (see Figure 4). This difference was statistically significant with a chi squared value of 4.7 (p = 0.03) by continuation ratio logistic regression.

**Satisfaction with the decision**

At the time of decision making, the SDP group and control group had a mean SWD score of 4.2 and 4.1 respectively (see Table 4). This difference was not statistically significant (p = 0.6).
Figure 4: Patients’ Responses to the question “Who made this treatment decision?”

**IHD SDP Group**

<table>
<thead>
<tr>
<th>Role in decision</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>49</td>
</tr>
<tr>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>5</td>
<td>9</td>
</tr>
</tbody>
</table>

**Control Group**

<table>
<thead>
<tr>
<th>Role in decision</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>12</td>
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<td>3</td>
<td>40</td>
</tr>
<tr>
<td>4</td>
<td>23</td>
</tr>
<tr>
<td>5</td>
<td>19</td>
</tr>
</tbody>
</table>

**Key to Responses**

1 You Alone  
2 Mostly you  
3 Doctor and you equally  
4 Mostly the doctor  
5 Doctor alone
Chapter IV: Discussion

In this randomized trial of the Ischemic Heart Disease Shared Decision Making Program (IHD SDP), we evaluated the impact of a decision aid, the IHD SDP, on the decision making process. Our sample population consisted of patients with ischemic heart disease who were facing a treatment decision about elective coronary revascularization for the first time. We compared the IHD SDP to usual patient-physician decision making. We hypothesized that the IHD SDP would assist in the shared decision making process. To test this hypothesis, we chose patient satisfaction with the decision making process as our primary outcome. We also measured other indicators of shared decision making which included: knowledge, decisional conflict, initial decision, patient role in decision and satisfaction with decision. All outcomes measures were collected at the time of treatment decision by standardized patient self administered reports.

Satisfaction with the decision making process

Does the IHD SDP improve satisfaction with the decision making process? No, we found no difference in our primary outcome between the intervention and control group at the time of treatment decision.

In the only other reported RCT of an SDP, patients' satisfaction with the decision making process (SwDMP) was improved. In that study of men with BPH, the mean SwDMP score was 76 % for the SDP group and 71 % for control group.24 This represented a statistically significant increase in satisfaction with the decision making process (p = 0.03). In our study, the SDP and control groups reported mean scores of 72 % and 70 % respectively, not a statistically significant difference (see Table 4).
Why the negative result? Lack of power is a common reason for negative trials, however our sample size population was only marginally smaller than the Barry BPH SDP trial, (n = 227).24 Furthermore, we are 95 % confident that the true difference is between -4 % and +7 % (see Table 4).

Another reason may be that no real difference exists. Although, this is our preliminary conclusion, there are some observations that raise uncertainty about this conclusion. The IHD SDP group showed higher knowledge scores, indicated greater involvement in decision making and showed a trend towards higher certainty that their information needs had been met. These positive indicators of shared decision making should, arguably, result in higher satisfaction with decision making. On the other hand, no overall difference in uncertainty and satisfaction with the decision made were observed between the groups.

Another reason for the negative result may relate to the reliability, validity and responsiveness of the SwDMP scale in our study population. The SwDMP scale was shown to be reliable and valid in men who were facing treatment decisions about BPH.24

It can be argued that treatment decisions for ischemic heart disease are associated with higher risks, more uncertainty and greater consequences in terms of patient mortality and quality of life. As a result the reliability, validity and responsiveness of the SwDMP scale in this “high risk” treatment decision may have been different than in the “low risk” BPH scenario. Further research, evaluating satisfaction scales in low and high risk decision making is warranted.
Furthermore, as stated by the authors of the BPH SDP trial the clinical significance of a five percent increase in SwDMP is unknown.\textsuperscript{34}

Another reason for the negative result may be due to the presence of a ceiling effect when measuring satisfaction. A general observation in this study was that, on average, patients in both groups reported relatively high satisfaction scores for both the SwDMP and SWD scales. Therefore, regardless of the intervention, patients are generally satisfied. This observation is supported by the work of Kraetschmer, who found that 416 patients undergoing coronary angiogram at TTH were overall generally satisfied with the physicians, care received and role in decision making.\textsuperscript{41}

Another possible explanation is that of cognitive dissonance. It is possible that once patients have made a conscious decision about treatment, their responses to satisfaction measures about the decision making process are influenced by the belief that the decision must be right regardless of whether it is right.

Finally, the negative result may be due in part to the possibility that the patients who had the most to benefit from the IHD SDP were the ones who dropped out of the study. According to Liao et al, patients with less education benefited the most from the IHD SDP in their study.\textsuperscript{23} In our trial, the drop-out group reported lower incomes and lower general health scores than those who completed the study.

**Patient knowledge**

Does the IHD SDP improve patients’ knowledge deemed necessary to an informed treatment decision? Yes, SDP patients scored significantly higher than controls on the multi-item knowledge scale, with a mean scores of 76 % and 62 % respectively.
(p < 0.005). This scale was administered at the time of treatment decision, at least one month after viewing the IHD SDP. IHD SDP patients apparently learned more than the controls and retained this knowledge throughout the decision making process.

This observation is consistent with the BPH SDP trial where at two weeks after viewing, SDP patients answered on average 75% of questions correctly, compared to 54% for controls (see Table 1).24

The IHD SDP was successful as a decision aid in assisting patients in acquiring knowledge deemed important in the decision making process. This observation offers support for the use of decision aids in promoting and improving the informed consent process.

Decisional conflict

Does the IHD SDP decrease patients’ uncertainty around the treatment decision? No, at the time of treatment decision, both groups had a mean score of 2.1 using the Decisional Conflict Scale. From previous studies, a score of 2.1 falls into the range of decision makers who would be more likely to delay their decision or are unsure of the decision, compared to those who have made their decision or are confident of their decision. However in these previous studies, relatively low stress decisions were studied (i.e. whether to receive immunization for influenza). For higher stress decisions such as the one our study patients faced, higher mean scores may be expected.19

According to the “Information Needs” sub-scale of the DCS, SDP patients indicated greater certainty that their information needs had been met compared to the controls, with scores of 1.8 and 2.1 respectively, lower scores indicating lower
uncertainty. Although not statistically significant after adjusting for multiple comparisons, it is consistent with the documented finding of higher mean knowledge scores in the SDP group.

**Initial treatment decision**

Does the IHD SDP affect patients' initial treatment decision? Perhaps, fewer SDP patients did indicate that they had chosen revascularization when compared to the control patients, 76 % vs. 59 % respectively (p = 0.02). This statistically significant difference was lost after adjusting for multiple comparisons. Furthermore, this observation represents what patients stated they had chosen and does not necessarily indicate the actual treatment performed.

We hypothesized that our patient population would rely heavily on the opinion of the physicians involved concerning coronary revascularization and that the rates of revascularization would be equally high in both the SDP and control groups, given the severity of the disease. However, from previous observational studies of the BPH SDP a 40-50 % reduction in rates of prostatectomy in sites that used the BPH SDP compared to control sites was reported.

**Patient satisfaction with the decision**

Does the SDP affect patients' satisfaction with the decision made? No, using the SWD scale, mean score of 4.2 and 4.1 were found for the SDP and control groups respectively (see Table 4). These mean scores imply high patient satisfaction with the decision and would predict a high patient certainty to carry out the decision.

**Patient role in decision making**
Does the IHD SDP affect patients' role in decision making? Yes, SDP patients indicated that they played a greater role in the decision making process than the control patients (see Figure 4). This observation provides further evidence that the IHD SDP can assist patients in becoming more active partners in decision making.
Chapter V: Study Limitations

Internal validity

A significant number of patients were lost to follow up, 25%. However, only a slightly higher drop-out rate was seen in the SDP arm compared to the control arm, 28% vs. 22% respectively, even though the IHD SDP arm required an extra visit to view the IHD SDP. Although our sample size requirement of 84 per group was met, despite the drop-out rate of 25%, the internal validity of our results may have been affected. The drop-out group reported lower incomes, lower general health and physical functioning scores, and higher bodily pain scores ($p \leq 0.05$). The omission of this group of patients may have biased the study results.

Selection bias was minimized by enrolling available consecutive eligible patients from the angiography department. Of the 279 eligible patients 240 consented and were enrolled in the study (86%).

Another theoretical threat to the internal validity was contamination, the possibility of the control group being exposed to the intervention, IHD SDP. This could have occurred if physicians as a result of having patients enrolled in the trial changed their usual decision making process and attempted to duplicate the intervention. We do not believe this occurred for two reasons. First, the IHD SDP is a highly technical, structured, in-depth personalized interactive experience that lasts over sixty minutes in duration and is therefore difficult to duplicate. Second, there were over thirty attending cardiologists and cardiovascular surgeons involved, the probability of a significant number of them changing their practice behavior during the duration of this trial is low.
The absence of blinding may have also threatened the internal validity of the trial. Patients randomized to the SDP group may have been more motivated to learn and participate than those in the control group.

Despite these limitations, successful randomization of study patients was achieved (see Table 2) and standardized baseline and decision questionnaires were completed for 180 of the 240 patients enrolled.

**Generalizability**

The majority of participants in this trial were men (see Table 3). The main reason for this was not because women refused to participate but rather because women in the target population did not undergo coronary angiography at the same rate as men. This observation is consistent with the work of Jaglal et al., who have shown that women undergo coronary angiography at a significantly lower rate than men in Ontario and that other gender based differences exist in the diagnostic work-up of ischemic heart disease.\textsuperscript{42,43}

The study population was limited to English speaking patients. If decision aids are to become more widely accepted this issue must be addressed. This study was also limited to patients who were considered elective candidates for revascularization. For patients who are faced with a more urgent treatment decision, the value of the IHD SDP is unknown. The study population was also limited to first time decision makers. The results of this trial should not be generalized to patients who have faced the decision before, since their information needs and role in decision making may be significantly different.
Finally, for SDPs to remain accurate must be updated as new information important to decision making is acquired. For example, the IHD SDP does not discuss in depth the treatment option of coronary artery stenting, a procedure that has become an important option in revascularization.
Chapter VI: Further Research

A follow-up study is currently underway to confirm the rates of revascularization and patient health status, six months post decision. If the trend of decreased revascularization in the SDP group is confirmed, an economic evaluation on the impact of SDPs would be warranted.

We also wish to compare the recommendation of the cardiologist at the time of angiogram with the initial treatment choice of the patient and final treatment decision at six months. Since a trend towards medical therapy was seen in the SDP group, it will be important to correlate that finding with the physicians’ recommendation if that trend persists at six months.

The six month follow-up study will also measure patients' SwDMP, SWD and satisfaction with medical care received. Furthermore, we will examine the impact of the SDP on patients' role in decision making by comparing the scores obtained on problem solving and decision making at baseline with scores obtained at six months. The Deber Problem Solving Decision Making Scale will be used for this purpose. Scores at baseline are shown in Table 6 and indicate no difference between the control and SDP groups. The baseline results do support the distinction between problem solving and decision making and that patients wish to play a more active role in decision making. We wish to determine if patients exposed to the SDP will show higher decision making scores than the control group at six months. This is of interest since the results of the present study revealed that patients exposed to the SDP were more likely to indicate a more active role in decision making (see Figure 4).
<table>
<thead>
<tr>
<th>Problem Solving</th>
<th>Control Group (N=94) mean score</th>
<th>SDP Group (N=86) mean score</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>diagnosis</td>
<td>2.0</td>
<td>1.9</td>
<td>0.6</td>
</tr>
<tr>
<td>treatments</td>
<td>2.2</td>
<td>2.1</td>
<td>0.5</td>
</tr>
<tr>
<td>risks/benefits</td>
<td>2.1</td>
<td>2.0</td>
<td>0.5</td>
</tr>
<tr>
<td>probabilities</td>
<td>1.8</td>
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<tr>
<td>Decision Making</td>
<td></td>
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</tr>
<tr>
<td>Utilities</td>
<td>3.1</td>
<td>2.9</td>
<td>0.4</td>
</tr>
<tr>
<td>What is done</td>
<td>2.8</td>
<td>3.0</td>
<td>0.4</td>
</tr>
</tbody>
</table>
We are also conducting a pilot study of the linear VHS video version of the IHD SDP. A comparison of the two formats of the IHD SDP should provide additional information about the usefulness of this decision aid. To date, 30 patients have viewed the video at home and have completed the baseline and decision questionnaires.

Further analysis of the DSI, SwDMP, SWD and DCS scales are also planned. Correlation amongst and within the measures will be explored. A priori hypotheses on which items should be most responsive to the impact of decision aids will be elicited from several experts in shared decision making.

In this trial we hypothesized that patient satisfaction with the decision-making process would serve as a global indicator of the effectiveness of the IHD SDP. The results revealed no difference in this primary outcome between the control and intervention group. However, the results also showed the IHD SDP improved knowledge and showed a trend towards improving certainty that patients' information needs had been met and assisting patients in attaining a more active role in the decision-making process. These observations may suggest that a more appropriate global indicator of the effectiveness of decision aids is patient ownership in the decision-making process rather than patient satisfaction with the decision-making process. Further research into the parameters of satisfaction and ownership would be helpful.
Chapter VII: Implications

There are several implications of the results of this trial. From an ethical perspective, the IHD SDP improved patients' knowledge important for an informed decision, suggesting decision aids can play an important role in enhancing the informed consent process.

From a clinical perspective, the IHD SDP provided a feasible process to overcome some of the obstacles to successful shared decision making. Specifically, the IHD SDP helped meet the specific information needs of patients, was successfully incorporated into the busy world of clinical practice, was acceptable to both patients and physicians in terms of format and content and was presented at an appropriate time in decision making.

From a theoretical perspective, this trial provides a model for the evaluation of decision aids and raises further research questions about the measurement of satisfaction as an indicator of effective decision making.

From a health economic perspective, if the trend of decreased revascularization in the SDP group is confirmed, an economic evaluation on the impact on utilization of health care resources through the widespread use of SDPs would be warranted.
Chapter VIII: Conclusions

We conclude that the Ischemic Heart Disease Shared Decision Making Program, when compared to usual patient-physician decision making, did not increase patients' satisfaction with the decision making for patients with ischemic heart disease who were considering a treatment decision.

We also conclude that patients exposed to the Ischemic Heart Disease Shared Decision Making Program were more knowledgeable about their condition and treatment choices than control patients but did not differ in terms of uncertainty with decision making and satisfaction with the decision made at the time of treatment decision.

Finally, we conclude that those exposed to the Ischemic Heart Disease Shared Decision Making Program showed trends towards a more active role in the decision making process, more certainty that their information needs had been met and chose medical therapy over revascularization more often than the control group.
Chapter IX: References


41. Kraetschmer N. Preferences of patients undergoing angiogram for participation in treatment decisions: Coping style and the problem solving-decision making scale. 1994; 52 p. University of Toronto. Graduate Dept. of Community Health.


APPENDIX A

ETHICAL APPROVAL

CONSENT FORM
March 24, 1995

Dr. A. Detsky
en-g-246

Dear Dr. Detsky:

RE: 94-H001 A Randomized Controlled Trial of the Shared Decision Making Process for Stable Angina Patients Considering Elective Revascularization

I am pleased to inform you that the above mentioned research protocol which is a continuation of Re: 94-H001 Patient Participation in the Evaluation of the Shared Decision-Making Program on Stable Angina has been approved by the Executive of The Toronto Hospital Committee for Research on Human Subjects.

Best wishes for the successful completion of your project.

Yours sincerely,

(Mrs.) M. Evis
Administrative Assistant
Research Directorate

cc: Dr. M. Morgan
PATIENT CONSENT FORM

A randomized trial of the shared decision making process for stable angina patients considering revascularization.

I, ___________________________ have been asked to participate in this research study that is comparing the stable angina video disc (SAVD) to conventional ways of providing information.

The purpose of this study is to see if SAVD helps patients and physicians in the decision making process on treatment choices for stable angina.

I am eligible for this study because I have recently undergone a coronary angiogram that shows that I am a candidate for either coronary artery bypass surgery and/or angioplasty. However neither of these procedures is required emergently but rather is considered elective, giving my physician and I more time to consider the options which also include continuing medical therapy alone.

SAVD is a newly developed way to provide patients with stable angina, like me, with information about my heart condition and the treatment options. SAVD presents information about the possible risks and benefits associated with the three treatment options: medical therapy, bypass surgery and angioplasty. The estimates of the likelihood of those risks and benefits are tailored to my situation by inputting information about my condition into the program prior to viewing, for example, the results of my recent angiogram.

If I agree to participate in this study, I understand that I have an equal chance of being assigned to viewing SAVD or not.

If assigned to viewing SAVD I will require one additional appointment at TTH to see the program. This appointment will occur within the next four weeks. The viewing session of SAVD will take less than two hours to complete. I will be offered reimbursement for parking.

If I am not assigned to viewing SAVD I will not require an additional appointment at the TTH.

Regardless of whether I view SAVD, I will receive the necessary information about my heart condition and treatment options from my physicians.

I understand that my physicians will be aware of my participation in this study. They will provide the necessary information about my heart condition and continue to follow me during the study as appropriate.

Regardless of whether or not I participate in this study I will continue to receive the same care I would usually receive by my physicians and The Toronto Hospital.
My participation in this study is completely voluntary and both I and my physician are free to refuse to take part or withdraw from the study at any time without affecting my current or future medical care.

I understand that all results of this study will be confidential. No information will be released or printed that would disclose my personal identity without my permission. A summary of the study's results will be offered to me when available.

I agree to complete the questionnaires that are needed for this study. These questionnaires will be completed in person or by mail (postage paid) or phone at various times over the next year. All information collected is confidential.

A research coordinator has discussed the study with me and all of my questions have been answered. If I have any further questions a research coordinator is available at the phone numbers listed below.

I have read and understand the contents of this consent form. A copy of it has been given to me to keep. I hereby agree to participate in this study.

Signature: __________________________

Witness: __________________________

Date: __________________________

Research Coordinator: Dr. Matthew W. Morgan MD. 340 4357
Principal Investigator: Dr. Allan S. Detsky MD., PhD. 340 4667
APPENDIX B

CHECKLIST

REFERRAL FORM
If this patient has stable angina and comprehends English please answer the following questions.

If all answers are NO and you are REFERRING this patient for BYPASS SURGERY AND/OR ANGIOPLASTY please complete the attached referral form.

Any questions please call 4357 or 8950, or page Dr. Matt Morgan at 761 3013

PI: Allan S. Detsky MD, PhD
ph. 340 4667
Please indicate which treatments are possible options for this patient?

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONGOING MEDICAL THERAPY ALONE</td>
<td>_____</td>
</tr>
<tr>
<td>ELECTIVE BYPASS SURGERY</td>
<td>_____</td>
</tr>
<tr>
<td>ELECTIVE ANGIOPLASTY</td>
<td>_____</td>
</tr>
<tr>
<td>UNSURE</td>
<td>_____</td>
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</tbody>
</table>

If you are recommending a treatment at this time, please indicate which one.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Option</th>
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</thead>
<tbody>
<tr>
<td>ONGOING MEDICAL THERAPY ALONE</td>
<td>_____</td>
</tr>
<tr>
<td>ELECTIVE BYPASS SURGERY</td>
<td>_____</td>
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<tr>
<td>ELECTIVE ANGIOPLASTY</td>
<td>_____</td>
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</table>

The following patient information is required.

<table>
<thead>
<tr>
<th>Information</th>
<th>Option</th>
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</thead>
<tbody>
<tr>
<td>LV Function (grade):</td>
<td>1_____ 2____ 3____ 4____</td>
</tr>
<tr>
<td>LVEDP (if known):</td>
<td>_____</td>
</tr>
<tr>
<td>Coronary Anatomy, left L, right R, balanced B:</td>
<td>_____</td>
</tr>
</tbody>
</table>

Stenosis (highest percentage from most recent angiogram)

<table>
<thead>
<tr>
<th>Location</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Main</td>
<td>_____</td>
</tr>
<tr>
<td>Proximal Left Anterior Descending</td>
<td>_____</td>
</tr>
<tr>
<td>Left Anterior Descending</td>
<td>_____</td>
</tr>
<tr>
<td>Left Circumflex</td>
<td>_____</td>
</tr>
<tr>
<td>Posterior Descending</td>
<td>_____</td>
</tr>
<tr>
<td>Right</td>
<td>_____</td>
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</table>
### ANGINA: Canadian Cardiovascular Society Functional Classification

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<tr>
<th></th>
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### CHF: New York Heart Association Functional Classification

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### Mitral Regurgitation

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<tr>
<th></th>
<th>0</th>
<th>1+</th>
<th>2+</th>
<th>3+</th>
<th>4+</th>
</tr>
</thead>
</table>

### Comorbidities (indicate all conditions present)

- **Diabetes:**
- **Liver disease:**
- **Renal disease:**
- **Peripheral vascular disease:**
- **Cerebral vascular disease:**
- **Peptic ulcer disease:**
- **with sequelae:**

### Research Coordinators:

Matthew Morgan MD ph. 4357 pg. 761 3013  
Nancy Kraetschmer MSc. ph. 8950

Thank you from the SAVD Investigators

Alan S. Detsky MD, Peter Gladstone MD,  
R.J. Cusimano MD., Raisa B. Deber PhD,  
Hilary A. Llewellyn-Thomas PhD.

Signature of physician who completed referral:
PATIENT BACKGROUND QUESTIONNAIRE
FOR
STABLE ANGINA
A SHARED DECISION-MAKING PROJECT
THE TORONTO HOSPITAL

PATIENT ID NUMBER: _________
TODAY'S DATE: _________
(day/month/year)
Please complete this questionnaire
and return it to us in the postage paid envelope provided.

If you have any questions, please call
Dr. Matthew Morgan at 416 340 4357

Thank you!
Please take your time to carefully answer all the questions in this questionnaire to the best of your ability.

Thank you for participating in this research study.

1. How old were you on your last birthday?
   
   _______(years)

2. Overall, how would you rate your health now? (Circle One Number)

   1 Excellent  2 Very Good  3 Good  4 Fair  5 Poor

3. Have you ever experienced discomfort that has been diagnosed by a physician as **angina**? (Circle One Number)

   1. YES  2. NO

If YES,

In what month and year did a physician first tell you that you had angina?

   _______/_______
   month       year

4. At the present time, which ONE of the following four descriptions best describes your angina? (Circle One Number)

   1. Ordinary physical activity, such as walking and climbing stairs does not result in angina. I may experience angina with strenuous or rapid or prolonged exertion at work or recreation.

   2. My ordinary activity is slightly limited by angina. I may experience angina when I walk or climb stairs rapidly, walk uphill, walk or climb stairs after meals, or in the cold, or in the wind, or under emotional stress, or only during the few hours after awakening. I may also experience angina when I walk more than 2 blocks on the level or climb more than 1 flight of stairs at a normal pace and in normal conditions.

   3. My ordinary activity is markedly limited by angina. I may experience angina when I walk 1 or 2 blocks on the level and climb 1 flight of stairs in normal conditions at a normal pace.

   4. I am only able to carry on limited physical activity without experiencing angina. I may even experience angina at rest on occasion.
5. How would you rate your current knowledge about your heart condition?  
   (Circle One Number)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Little Knowledge</td>
<td>Very Knowledgeable</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. How would you rate your current knowledge about the treatment options available for your heart condition?  (Circle One Number)

<table>
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<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Little Knowledge</td>
<td>Very Knowledgeable</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. How would you rate your current knowledge about the risks and benefits for each of these treatment options?  (Circle One Number)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Little Knowledge</td>
<td>Very Knowledgeable</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. How certain are you about the treatment you prefer for your heart condition?  (Circle One Number)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>Very Certain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certain</td>
<td>Certain</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. What is your marital status now? (Circle One Number)
   1. Never Married
   2. Married or Common-law
   3. Separated
   4. Divorced
   5. Widowed

10. What is the highest year or grade in school completed? (Circle One Number)
    1. Elementary School or Less (grade 8 or less)
    2. Some High School
    3. Completed High School
    4. Some University/College
    5. Completed University/College
    6. Advanced Degree

11. What is your annual household income? (Circle One Number)
    1. Less than $20 000
    2. $20 000 - 40 000
    3. $40 000 - 60 000
    4. $60 000 - 80 000
    5. More than $80 000
12. Please answer the following questions about your attitudes towards participating in the decision making process with your doctor(s).

With regards to your heart condition: *(Circle One Number For Each Question)*

<table>
<thead>
<tr>
<th></th>
<th>only the doctor</th>
<th>mostly the doctor</th>
<th>doctor and you equally</th>
<th>mostly you</th>
<th>only you</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who should determine (diagnose) what the likely cause of your symptoms are?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Who should determine what the treatment options are?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Who should determine what the risks and benefits for each treatment option are?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Who should determine how likely each of these risks and benefits are to happen?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Given the risks and benefits of these possible treatments, who should decide how acceptable those risks and benefits are for you?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Given all the information about risks and benefits of the possible treatments, who should decide which treatment option should be selected?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
13. Based on what you know about your heart condition, what is your current opinion about the treatment you prefer? Please read each of the following statements and select the one that most accurately reflects how you currently feel. Ignore the angioplasty statements if it is not an option for you. (Circle One Number)

1. definitely prefer bypass surgery
2. probably prefer bypass surgery
3. definitely prefer angioplasty
4. probably prefer angioplasty
5. definitely prefer ongoing medical therapy alone
6. probably prefer ongoing medical therapy alone
7. no preference
8. not sure

14. If you had to choose one therapy today, which would it be? (Circle One Number)

1. bypass surgery
2. angioplasty
3. ongoing medical therapy alone
4. not sure
SF-36 HEALTH SURVEY

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(circle one)

Excellent ................................................... 1
Very good ..................................................... 2
Good .......................................................... 3
Fair ............................................................ 4
Poor ............................................................ 5

2. Compared to one week ago, how would you rate your health in general now?

(circle one)

Much better now than one week ago ................................................... 1
Somewhat better now than one week ago ........................................ 2
About the same as one week ago ..................................................... 3
Somewhat worse now than one week ago ........................................ 4
Much worse now than one week ago ................................................ 5
3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>ACTIVITIES</th>
<th>Yes, Limited A Lot</th>
<th>Yes, Limited A Little</th>
<th>No, Not Limited At All</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>c. Lifting or carrying groceries</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>d. Climbing several flights of stairs</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>e. Climbing one flight of stairs</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>f. Bending, kneeling, or stooping</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>g. Walking more than a kilometre</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>h. Walking several blocks</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>i. Walking one kilometre</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>j. Bathing or dressing yourself</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

4. During the past week, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Cut down on the amount of time you spent on work or other activities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>b. Achieved less than you would like</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>c. Were limited in the kind of work or other activities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>d. Had difficulty performing the work or other activities (for example, it took extra effort)</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
5. During the past week, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

| a. Cut down the amount of time you spent on work or other activities | YES | NO |
| b. Accomplished less than you would like | 1   | 2   |
| c. Didn't do work or other activities as carefully as usual | 1   | 2   |

6. During the past week, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all ............................................................. 1
Slightly ........................................................................ 2
Moderately ..................................................................... 3
Quite a bit ....................................................................... 4
Extremely ....................................................................... 5

7. How much bodily pain have you had during the past week?

None ............................................................................. 1
Very mild ......................................................................... 2
Mild ................................................................................ 3
Moderate ......................................................................... 4
Severe ............................................................................ 5
Very severe ...................................................................... 6
8. During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?

   (circle one)

   Not at all .................................................. 1
   A little bit .................................................. 2
   Moderately ................................................... 3
   Quite a bit .................................................... 4
   Extremely ...................................................... 5

9. These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past week -

   (circle one number on each line)

<table>
<thead>
<tr>
<th></th>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>A Good Bit of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Did you feel full of pep?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>b. Have you been a very nervous person?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>c. Have you felt so down in the dumps that nothing could cheer you up?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>d. Have you felt calm and peaceful?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>e. Did you have a lot of energy?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>f. Have you felt downhearted and blue?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>g. Did you feel worn out?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>h. Have you been a happy person?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>i. Did you feel tired?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>
10. During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

11. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Don't Know</th>
<th>Mostly False</th>
<th>Definitely False</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I seem to get sick a little easier than other people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>b. I am as healthy as anybody I know</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>c. I expect my health to get worse</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>d. My health is excellent</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
APPENDIX D

PHYSICIAN SUMMARY FORM
Treatment Choices for Ischemic Heart Disease

Physician’s Note for: [Redacted], MD
Re: [Redacted]
Date: January 1, 1996

Patient Background Information

[Redacted] viewed the Shared Decision-making Program on January 1, 1996. The background information entered into the computer from his Referral Form determined his presentation. The information that was entered is listed below to enable you to confirm that the patient received accurate information from the program.

Physician: [Redacted]
Patient: [Redacted]
53 year old male, 5'11" tall, 200 pounds.
No prior CABG.
Chest Pain: Present.
NOT SUITABLE for angioplasty.
Ejection Fraction: 50  LVEDP: 18
Right dominant or balanced, (assumed)
Percentage of stenosis, by location:
  Left Main: 0  Left Circumflex: 75
  LAD: 0  Proximal LAD: 30
  Right: 0  Posterior Descending: 90
NYHA Class: 1
Mitral Insufficiency: NONE
Clinical Status: Stable angina.
The following general messages are presented to all patients who view the program:

- Bypass surgery has been shown to provide patients with longer-lasting angina relief than medical therapy.

- Few comparisons of the effectiveness of angioplasty, surgery, and medical therapy in providing relief of angina are currently available. For some patients, angioplasty and surgery seem to be equally effective, at least in the short term.

- The short-term risk of death is lower for medical therapy than it is for bypass surgery or angioplasty because these procedures carry the immediate risks of heart attack, stroke, or death.

- In general, people who are at greater risk, either because of the location of the coronary blockages or their overall heart condition, benefit more from surgery.

- Studies directly comparing survival after angioplasty to surgery and medical therapy have only recently begun, so our confidence about those comparisons is not as high as it is for the other treatments. Current information indicates that angioplasty and bypass surgery show slight advantages over medical therapy in increasing survival rates for patients with two blocked coronary arteries.

- Regardless of treatment type, existing coronary blockages may get worse, or new ones may develop over time. Lifestyle changes may enhance treatment effectiveness.

- This patient was presented with an estimate of their probability of surviving the bypass procedure: for patients of the same age with a similar medical condition, approximately 994 of 1000 would survive and 6 of 1000 would not survive.

- This patient chose NOT to view charts illustrating survival rates for patients medically similar to him. A copy of this chart has been provided to you as the last page of this document.
In addition to viewing the core program presentations on the potential benefits and risks of medical therapy, bypass surgery, and angioplasty, this patient watched the optional sections of the program that are indicated with an "X":

(X) What You Can Do: Making Lifestyle Changes
(X) Side Effects of Medical Therapy
(X) Bypass Surgery: What to Expect
(X) Angioplasty: What to Expect
This chart compares the effectiveness of the treatments in increasing survival for a group medically similar to your patient.

Number of Survivors

Years

<table>
<thead>
<tr>
<th>Years</th>
<th>Medical</th>
<th>Bypass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>1</td>
<td>80</td>
<td>50</td>
</tr>
<tr>
<td>2</td>
<td>60</td>
<td>30</td>
</tr>
<tr>
<td>3</td>
<td>40</td>
<td>20</td>
</tr>
<tr>
<td>4</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>
APPENDIX E

KEY TO SCORING OUTCOME MEASURES
PATIENT DECISION QUESTIONNAIRE
KEY TO SCORING

d - decision questionnaire
c - reversed score

For example d2.4c refers to question 2.4 in the decision questionnaire and its score was reversed (i.e. 1 becomes 5).

**Satisfaction with the Decision Making Process (SwDMP)**

Raw Score = d2.4c + d2.5c + d2.6c + d2.7c + d2.8c + d3.1c + d3.2c + d3.3c + d3.4c + d3.5c + d3.6c + d3.7c

Final Score = ((Raw Score -12) / 48) X 100 %

**Knowledge (Surgery/Angioplasty/Medical)**

Raw Score = d10.1c + d10.2c + d10.3c + d10.4c + d10.5c + d10.6c + d10.7c + d10.8c + d10.9c + d10.10c + d10.11c + d10.12c + d10.13c + d10.14c + d10.15c + d10.16c + d10.17c + d10.18c + d10.19c + d10.20c

Final Score = (Raw Score / 20) X 100 %

**Knowledge (Surgery/Medical)**

Raw Score = d10.1c + d10.2c + d10.3c + d10.4c + d10.5c + d10.6c + d10.7c + d10.8c + d10.9c + d10.10c + d10.11c + d10.12c + d10.13c + d10.14c + d10.15c

Final Score = (Raw Score / 15) X 100 %

**Satisfaction with Decision (SWD)**

Raw Score = d4.1c + d4.2c + d4.3c + d4.4c + d4.5c + d4.6c

Final Score = Raw Score / 6
Decisional Conflict (DCS)

Raw Score = d5.1c + d5.2c + d5.3 + d5.4 + d5.5 + d5.6 + d5.7c + d5.8 + d5.9 + d5.10c + d5.11c + d5.12 + d5.13 + d5.14 + d5.15 + d5.16

Final Score = Raw Score / 16

DCS Subscales

unsure  (d5.1c + d5.2c + d5.3) / 3
info    (d5.4 + d5.5 + d5.6) / 3
values  (d5.8 + d5.9 + d5.10c) / 3
support (d5.7c + d5.11c + d5.12) / 3
effective (d5.13 + d5.14 + d5.15 + d5.16) / 4
PATIENT DECISION QUESTIONNAIRE

FOR

STABLE ANGINA

A SHARED DECISION-MAKING PROJECT

THE TORONTO HOSPITAL

PATIENT ID NUMBER: __________

TODAY'S DATE: __________

(day/month/year)
Please complete this questionnaire and return it to us in the postage paid envelope provided.

If you have any questions, please call Dr. Matthew Morgan at 416 340 4357

Thank you!
Please take your time to carefully answer all the questions in this questionnaire to the best of your ability.

Feel free to contact us if you have any questions or comments.

Please return this questionnaire in the postage paid envelope provided.

Thank you for participating in this research study.

Dr. Matthew W. Morgan 340 4357

1. Which of the following options have you decided upon for the treatment of your heart condition? *(Circle One Number)*

<table>
<thead>
<tr>
<th>Number</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>bypass surgery</td>
</tr>
<tr>
<td>2</td>
<td>angioplasty</td>
</tr>
<tr>
<td>3</td>
<td>ongoing medical therapy alone</td>
</tr>
</tbody>
</table>

1b. Who made this treatment decision? *(Circle One Number)*

<table>
<thead>
<tr>
<th>Number</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>You alone</td>
</tr>
<tr>
<td>2</td>
<td>Mostly you</td>
</tr>
<tr>
<td>3</td>
<td>Your doctors and you equally</td>
</tr>
<tr>
<td>4</td>
<td>Mostly your doctors</td>
</tr>
<tr>
<td>5</td>
<td>Your doctors alone</td>
</tr>
</tbody>
</table>
2. Please tell us how strongly you agree or disagree with the following statements. Many of the statements refer to the decisions about treatment for your heart condition since entering this study. (Circle One Number for each statement)

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I am very satisfied with the medical care I receive.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>There are some things about the medical care I receive that could be better.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>All things considered, the medical care I receive is excellent.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>I got as much information as I wanted about my heart condition.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>I am satisfied that I was adequately informed about the different treatments available for my heart condition.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>I had as much input as I wanted in the choice of treatments for my heart condition.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7</td>
<td>I am satisfied that my own opinion was important in the decision about treatment for my heart condition.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8</td>
<td>Looking back, I think I relied too much on the opinion of my doctors in deciding which treatment to choose.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9</td>
<td>Looking back, I think the right treatment choice was made.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10</td>
<td>I am satisfied with the decision that was made about treatment for my heart condition.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
3. Please answer the following questions as they pertain to your decision about treatment for your heart condition and the medical care you've received since entering this study. *(Circle One Number for each statement)*

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>How would you rate the explanations of medical procedures and tests for your heart condition?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>How would you rate the personal interest in you and your medical problems by your doctors and staff?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>How would you rate the reassurance and support offered to you by your doctors and staff?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>How would you rate the amount of time you had with your doctors and staff during visits?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>How would you rate the amount of help you got dealing with your heart condition?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>How would you rate the amount of information you got about your heart condition and its treatments?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>How would you rate the attention given to what you had to say about your heart condition?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>How would you rate the treatment decision for your heart condition that was made?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
4. We would now like to know how satisfied you are with the decision you made concerning treatment for your heart condition. Please show how strongly you agree or disagree with each of the following statements. *(Circle One Number for each statement)*

<table>
<thead>
<tr>
<th></th>
<th>I am satisfied that I am adequately informed about the issues important to my decision.</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>The decision I made was the best decision possible for me personally</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>I am satisfied that my decision was consistent with my personal values.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>I expect to successfully carry out the decision I made.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>I am satisfied that this was my decision to make.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>I am satisfied with my decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>
5. Now, thinking about the choice you made, please look at the following comments some people make when deciding about treatments. Please show how strongly you agree or disagree with these comments by CIRCLING THE NUMBER from 1 (strongly agree) to 5 (strongly disagree) that best shows how you feel about the decision you made for your heart condition. (Circle One Number for each statement)

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>This decision is hard for me to make</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>I'm unsure what to do in this decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>It's clear what choice is best for me.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>I'm aware of the choices I have to treat my heart condition.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>I feel I know the benefits of each treatment.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>I feel I know the risks and side effects of each treatment.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7</td>
<td>I need more advice and information about the choices.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8</td>
<td>I know how important the benefits of the treatment options are to me in this decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9</td>
<td>I know how important the risks and side effects of the treatment options are to me in this decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10</td>
<td>It is hard to decide if the benefits are more important to me than the risks, or if the risks are more important than the benefits.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>11</td>
<td>I feel pressure from others in making this decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>12</td>
<td>I have the right amount of support from others in making this decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>13</td>
<td>I feel I have made an informed decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>14</td>
<td>My decision shows what is most important for me.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>15</td>
<td>I expect to stick with my decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>16</td>
<td>I am satisfied with my decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>17</td>
<td>I trust my physicians more since making this decision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
6. How would you rate your current knowledge about your heart condition? *(Circle One Number)*

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Little</strong></td>
<td><strong>Very</strong></td>
<td><strong>Knowledgeable</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Knowledge</strong></td>
<td><strong>Knowledgeable</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. How would you rate your current knowledge about the treatment options available for your heart condition? *(Circle One Number)*

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Little</strong></td>
<td><strong>Very</strong></td>
<td><strong>Knowledgeable</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Knowledge</strong></td>
<td><strong>Knowledgeable</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. How would you rate your current knowledge about the risks and benefits for each of these treatment options? *(Circle One Number)*

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Little</strong></td>
<td><strong>Very</strong></td>
<td><strong>Knowledgeable</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Knowledge</strong></td>
<td><strong>Knowledgeable</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. How certain are you about the treatment you prefer for your heart condition? *(Circle One Number)*

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Not at all</strong></td>
<td><strong>Very</strong></td>
<td><strong>Certain</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Certain</strong></td>
<td><strong>Certain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10. Please read each statement carefully. Circle 'T' for True, 'F' for False, or if you are unsure of the answer, circle '?' (don't know). Please do not guess.

1. Coronary artery disease is caused by plaques (deposits) that block the blood vessels which surround and supply the heart muscle (the coronary arteries). ...................................................... T  F  ?

2. Coronary artery disease does not cause serious complications such as heart attack or death. ...................................................... T  F  ?

3. Coronary artery disease itself can be cured by a number of treatments including angioplasty and bypass surgery. .......... T  F  ?

4. Most patients who choose ongoing medical therapy alone are often able to discontinue their medication after a few years. .......... T  F  ?

5. Medical therapy is almost always successful in completely relieving angina. ................................................................. T  F  ?

6. By choosing medical therapy now, a person will be unable to have either bypass surgery or angioplasty in the future. ............... T  F  ?

7. Possible side effects from medical therapy include fatigue, headache, decreased concentration and sexual dysfunction. ...... T  F  ?

8. During surgery the blocked coronary arteries are bypassed, commonly using blood vessels from the leg and chest. .......... T  F  ?

9. Most patients who undergo bypass surgery are hospitalized for fewer than 5 days. ................................................................. T  F  ?

10. Each treatment option carries with it some risk of stroke, heart attack or death. ................................................................. T  F  ?
11. After bypass surgery or angioplasty, "lifestyle" changes (e.g., diet, smoking cessation, regular exercise) are not as important as when medical therapy is used. ................................................................. T  F  ?

12. If bypass surgery "works" and the patient has no angina 1 month later, this means that it is unlikely that the angina will ever return. ............ T  F  ?

13. When compared with medical therapy, bypass surgery has a higher risk of immediate complications (such as heart attack, stroke, or death). ...... T  F  ?

14. Bleeding requiring a blood transfusion may occur with bypass surgery. ................................................................. T  F  ?

15. After bypass surgery some patients experience difficulty concentrating and some memory loss, which usually resolves. ....... T  F  ?

16. Angioplasty is similar to an angiogram, but is a more complicated procedure which involves inflating a balloon to open up a blocked artery. ................................................................. T  F  ?

17. If angioplasty "works" and the patient has no angina 1 month later, this means that it is unlikely that the angina will ever return. ......... T  F  ?

18. When compared with medical therapy, angioplasty has a higher risk of immediate complications (such as heart attack, stroke, or death). T  F  ?

19. Some angioplasty patients may require repeat angioplasty or even bypass surgery in the future. ......................................................... T  F  ?

20. Occasionally an artery can be damaged during angioplasty and emergency bypass surgery is required. ......................................................... T  F  ?
10. Please read each statement carefully. Circle "T" for True, "F" for False, or if you are unsure of the answer, circle "?" (don't know). Please do not guess.

1. Coronary artery disease is caused by plaques (deposits) that block the blood vessels which surround and supply the heart muscle (the coronary arteries). ........................................ T  F  ?

2. Coronary artery disease does not cause serious complications such as heart attack or death. ........................................ T  F  ?

3. Coronary artery disease itself can be cured by a number of treatments including angioplasty and bypass surgery. .......... T  F  ?

4. Most patients who choose ongoing medical therapy alone are often able to discontinue their medication after a few years. ............ T  F  ?

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<p>| | | | | | | | | | |</p>
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