ORIGINAL ARTICLES

Randomized, Controlled Trial of an Interactive Videodisc Decision Aid for Patients with Ischemic Heart Disease

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OBJECTIVE: **To determine the effect of the Ischemic Heart Disease Shared Decision-Making Program (IHD SDP) an interactive videodisc designed to assist patients in the decision-making process involving treatment choices for ischemic heart disease, on patient decision-making.**

DESIGN: **Randomized, controlled trial.**

SETTING: **The Toronto Hospital, University of Toronto, Toronto, Ontario, Canada.**

PARTICIPANTS: **Two hundred forty ambulatory patients with ischemic heart disease amenable to elective revascularization and ongoing medical therapy.**

MEASUREMENTS AND MAIN RESULTS: **The primary outcome was patient satisfaction with the decision-making process. This was measured using the 12-item Decision-Making Process Questionnaire that was developed and validated in a randomized trial of the benign prostatic hyperplasia SDP. Secondary outcomes included patient knowledge (measured using 20 questions about knowledge deemed necessary for an informed treatment decision), treatment decision, patient-angiographer agreement on decision, and general health scores. Outcomes were measured at the time of treatment decision and/or at 6 months follow-up. Shared decision-making program scores were similar for the intervention and control group (71% and 70%, respectively; 95% confidence interval [CI] for 1% difference, −3% to 7%). The intervention group had higher knowledge scores (75% vs 62%; 95% CI for 13% difference, 8% to 18%). The intervention group chose to pursue revascularization less often (58% vs 75% for the controls; 95% CI for 17% difference, 4% to 31%). At 6 months, 52% of the intervention group and 66% of the controls had undergone revascularization (95% CI for 14% difference, 0% to 28%). General health and angina scores were not different between the groups at 6 months. Exposure to the IHD SDP resulted in more patient-angiographer disagreement about treatment decisions.**

CONCLUSIONS: **There was no significant difference in satisfaction with decision-making process scores between the IHD SDP and usual practice groups. The IHD SDP patients were more knowledgeable, underwent less revascularization (interventional therapies), and demonstrated increased patient decision-making autonomy without apparent impact on quality of life.**

KEY WORDS: **coronary disease; decision aids; computer-assisted decision making; randomized, controlled trials; angioplasty; coronary artery bypass; medical informatics.**
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Cardiovascular disease remains the leading cause of mortality in adults.[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 over the last decade.[2–4] In cases of severe coronary artery disease, 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.[5] However, with less severe disease this survival advantage is uncertain, so the optimal choice of treatment is less clear.[6–12] 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. To assist with these treatment challenges, decision aids have been developed based on the philosophy of shared decision making.[13,14] Examples of decision aids include decision boards, audiotape/booklets, linear videos, and interactive videodiscs.[13,15,16] The goal of decision aids is to present information necessary to informed and effective decision making in a structured, unbiased, and comprehensive format that also recognizes and incorporates patient participation and preference into the decision-making process. One such decision aid is the

Ischemic Heart Disease Shared Decision-Making Program (IHD SDP).

Descriptive reports of an earlier developed SDP on benign prostatic hyperplasia (BPH) revealed that men responded favorably and that prostatectomy rates declined when compared to historical data.[17,18] A recent prospective, randomized trial of the BPH SDP concluded that patients exposed to the SDP were better informed and were more satisfied with the decision-making process.[19] An observational study of the IHD SDP showed that the cohort of patients rated the SDP as helpful and felt increased confidence in their treatment choice.[20] A recently published randomized, controlled trial of a videotape version of the IHD SDP revealed that those who viewed the videotape were more knowledgeable but less satisfied with their treatment decision.[21] The IHD SDP represents the "state of the art" for informed decision making.[22] Ideally, if shared decision-making programs are to be widely accepted as an essential component of health care delivery, they must be shown to assist patients in informed and effective decision making, decrease unjustified practice variation, and result in higher quality health care. The purpose of our study was to conduct a prospective, randomized trial to evaluate the impact of the IHD SDP on patient decision making.

METHODS

Patient Population

Patient enrollment began August 22, 1995 and was completed June 27, 1996. Patients were eligible for inclusion if they were adults with a confirmed angiographic diagnosis of ischemic heart disease, defined as stenosis of more than 50% of at least 1 coronary artery, that could be treated by elective revascularization (bypass surgery and/or angioplasty) with the option of ongoing medical therapy. All patients were considering revascularization for the first time and comprehended written and spoken English. Patients were excluded if they had unstable angina pectoris (defined as angina occurring at rest, accelerated angina, or new-onset angina), required urgent or emergent revascularization for any reason (i.e., significant left main coronary artery disease, more than 50%), had previous bypass surgery or coronary angioplasty, or had an immediate postangiogram complication resulting in an unexpected hospital stay.

Ambulatory patients undergoing elective coronary angiography were recruited immediately following angiogram from The Toronto Hospital, Western Division. After informed consent to participate in this study was obtained, consenting patients 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.

Intervention

The IHD SDP is one of several SDPs produced by the Foundation for Informed Medical Decision Making (Hanover, NH). The design, content, and structure of SDPs have been described previously.[20,22] In summary, the IHD SDP is an interactive video program that presents information about the possible risks and benefits associated with three treatment alternatives for ischemic heart disease: medical therapy, bypass surgery, and angioplasty. The probability estimates of these risks and benefits are tailored to each patient's 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 outcome research and an extensive review of the published literature, as well as interviews with clinical investigators, experts in the field, and focus groups with patients. The version of the SDP used in this trial included evidence from randomized, controlled trials published up to 1994.[5–10,12] The IHD SDP incorporates filmed segments in which patients who have already faced the decision and are presently living with the resulting outcome share their experiences. Computer graphics are also incorporated to give patients a further understanding about their medical condition and probabilities of survival for different treatment options. Physicians and patients receive a summary of the important points covered by the IHD SDP, including survival and treatment complication estimates.

Patients randomized to the IHD SDP arm of the trial also received a brochure with educational information about the treatment choices. These patients were given an appointment to view the IHD SDP within 4 weeks after angiography. 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 the written summary was also provided.

Controls

To allow for a fair and realistic comparison of the IHD SDP to the present practice of decision making, patients randomized to the control group 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. This decision-making process consisted of further discussions and communications with a number of physicians, as described below.

Physicians

Each patient in this study had a primary care physician, a referring cardiologist, and a cardiologist who performed the angiogram. When appropriate, patients were also seen by an interventional cardiologist for consideration

of angioplasty and/or a cardiovascular surgeon for consideration of bypass surgery. As a result, each patient was exposed to numerous physician opinions. No attempt was made to control for physicians in this study or randomize within strata by physician. The number of physicians involved was simply too large to do this. All of the cardiologists and cardiovascular surgeons were certified specialists of the Royal College of Physicians and Surgeons. The group of physicians who had the greatest exposure to the study design and protocol were the cardiologists who performed the angiogram (angiographer). There were 18 angiographers involved in this study, all of whom agreed to patient enrollment.

Outcomes

The primary outcome of this study was patient satisfaction with the decision-making process at the time of treatment decision. We modified the 12-item Decision-Making Process Questionnaire that was developed and validated by Barry et al. in a randomized trial of the BPH SDP.[19] Modifications were minor, such as replacing the phrase "prostate problem" with "heart condition" in the corresponding items (see Appendix 1).

The secondary outcome of patient knowledge was measured at the time of treatment decision. We developed a set of 20 true/false items to assess knowledge deemed necessary for an informed treatment decision (see Appendix 2). This item set was reduced to 15 for patients who were not eligible for angioplasty. Prior to commencing this study, the criterion validity of this scale was assessed by measuring the improvement in scores on a cohort of 32 newly diagnosed ischemic heart disease patients before and after viewing a VHS video version of the IHD SDP. These patients had a mean score of 60% before viewing and 84% after viewing the SDP ($P = .01$).

The initial patient treatment preference and final treatment decision were recorded. Patients were contacted by phone at 6 months to determine what treatment was actually performed. The Medical Outcomes Study 36-item short-form health survey (SF-36) and the Canadian Cardiovascular Angina (CCVA) scales were used to assess general health and angina status.[23,24] To compare patient and angiographer treatment choice, the angiographer's treatment recommendation was recorded and compared to the patient's initial treatment preference.

Patients in both the intervention and control groups were given a baseline questionnaire at the time of randomization. Additional self-administered mail-back questionnaires were sent to all patients at the time of treatment decision and at 6 months. Telephone follow-up was completed as needed.

Statistical Analysis

The sample size calculation was based on analysis of the primary outcome (satisfaction with the decision-making process) with a two-tailed, two-sample, equal-variance t test. With a 5% risk of a type 1 error, 84 subjects per group were required to obtain 90% power to detect a medium effect, a difference of 0.5 standard deviation between groups.[25]

For each patient, a score representing overall satisfaction with the decision-making process was obtained by summing and normalizing the 12-item category rating scale to yield a score ranging from 0 to 100%. Then both the Wilcoxon rank sum test and t test were used to test for across-group differences in the satisfaction score at the time of treatment decision. The responses to the knowledge scale were also summed to provide a patient's score ranging from 0% to 100%, and the Wilcoxon rank sum test and t test were used to assess across-group differences in knowledge. Both statistical tests gave similar results, and results based on the t test are reported here.

The outcome of the patient's initial treatment decision and actual treatment at 6 months was grouped as either ongoing medical therapy or revascularization (bypass surgery and angioplasty). The number choosing each therapy and the number agreeing with the angiographer were reported as percentages of the total in each group, and P values for the differences between groups were calculated using Fisher's exact test. Confidence intervals for differences in proportions were based on normal approximations. Further analysis of agreement between the angiographer and the patient used a logistic regression model. Agreement (yes/no) was the outcome variable, and the predictor variables were the angiographer's recommended treatment, the intervention group, and a variable representing the interaction of these two terms. This allowed the assessment of whether the intervention affected the odds of agreement with a recommendation of surgical treatment differently from the odds of agreement with a recommendation of medical treatment.

Two secondary analyses of the main outcome were performed to estimate the effect due to intervention after adjusting for potential confounders. The first was a multiple regression that adjusted for clinical factors that appeared to differ somewhat between the two groups. The second was a regression analysis that was stratified by angiographer. An analysis was performed of treatment decisions at 6 months for those with 3 or more diseased coronary arteries compared to those with less than 3 diseased coronary arteries.

RESULTS

Patient Accrual and Follow-up

Of the 279 eligible patients, 240 consented and were enrolled in the study, yielding an 86% entrance rate (Fig. 1). The reasons given for nonconsent were not specific and included "inconvenience" and "lack of interest." One hundred twenty patients were randomized to the control arm and 120 to the SDP arm. In total, 53 of the 240 patients enrolled did not proceed with the study, representing a 22% entrance drop-out rate. Of these, 30 were enrolled in

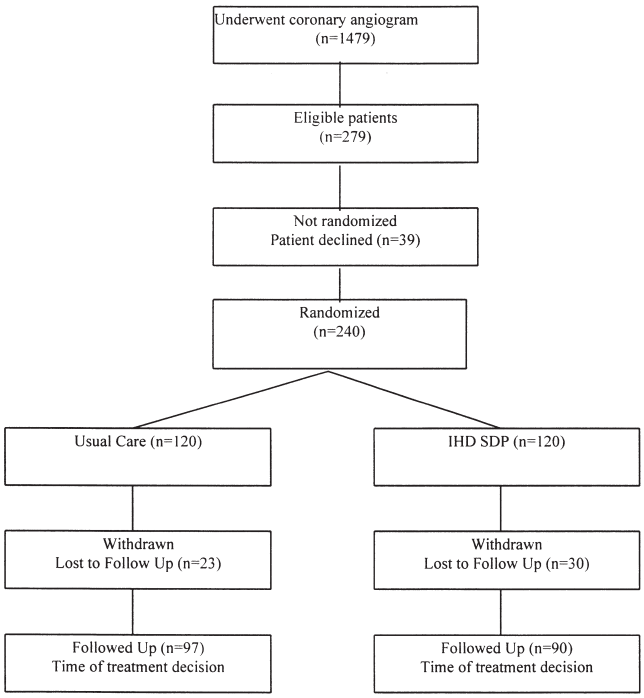

FIGURE 1. Profile of patient recruitment.

the SDP group and 23 in the control group. Reasons for dropping out of the study included the need for urgent revascularization (9 patients), not meeting inclusion criteria (3 patients), enrollment in another study (2 patients), moving (3 patients), incorrect randomization (1 patient), and patient refusal postrandomization (35 patients). Therefore, the results of this study are based on data from 187 patients (90 SDP, 97 control) who completed the trial, representing 78% complete follow-up at the time of initial treatment decision.

Baseline Characteristics

Baseline characteristics were available for 27 of the 53 patients who did not complete the study. Comparison to the 187 patients who completed the study revealed that the drop-out group reported lower incomes, lower general health and physical functioning scores, and higher bodily pain scores ($P < .05$). The baseline characteristics for the 97 control patients and the 90 SDP patients who completed the study are shown in Table 1. No statistically significant differences were found between the control and SDP groups at baseline.

Primary Outcome

At the time of treatment decision, the SDP group had a mean satisfaction with decision-making process score of 71%, compared with a mean of 70% for the control group; higher scores indicate greater satisfaction (Table 2). The 95% confidence interval for the true difference ranged from 3% in favor of the control group to 7% in favor of the SDP group.

Secondary Outcomes

At the time of treatment decision, the SDP group had a mean knowledge score of 75%, compared with a mean of 62% for the control group; higher scores indicate greater knowledge deemed important in decision making (Table 2). The 95% confidence interval for the true difference was 8% to 18% in favor of the SDP group.

Initially, 58% of the SDP group chose to pursue revascularization (either coronary artery bypass surgery or angioplasty); 75% of the control group chose revascularization (Table 3). The 95% confidence interval for the true difference ranged from 4% to 31% in favor of the control group. Six-month follow-up data from 181 patients revealed that this observation persisted, with mean revascularization rates of 52% in the SDP cohort compared with 66% in the control group (Table 3). The 95% confidence interval for the true difference ranged from 0% to 28% in favor of the control group. Despite this observation, there were no differences in angina scores and general health scores between the two groups at 6 months (Table 4).

Both groups reported a high level of agreement with the angiographer regarding the preferred initial treatment choice (82% agreement in the control group vs 69% in the SDP group, $P = .05$). The SDP group had higher agreement than the controls when the angiographer recommended medical treatment (91% vs 67%) and lower agreement than the controls when the angiographer recommended surgical treatment (65% vs 84%) (Table 5). In the logistic regression model, the P value for this interaction was .02. Despite this disagreement, when patients were asked to declare who made the final treatment decision, the SDP patients were as likely as the controls to respond that it was a shared decision between the patient and physician (83% vs 73%, respectively; $P = .3$).

Secondary Analyses

As expected, there were imbalances in the number of patients enrolled into the control group and interventional group when grouped by angiographer. A reanalysis of the primary outcome (SDMP) stratified by angiographer gave an estimated difference in SDMP between the two groups of 2.2% ($P = .4$). Because of the concern of possible clinical difference between the two groups in terms of left ventricular function, number of diseased arteries, and comorbidities, a secondary analysis of the primary outcome was performed adjusting for these variables. A multiple linear regression gave an estimated difference in satisfaction score of 2.1% ($P = .4$); none of the adjustment variables was significant ($F_{(6,179)} = 0.74$; $P = .6$). An analysis

Table 1. Comparison of Baseline Characteristics

	Control Group *n* = 97	SDP Group *n* = 90	*P* Value
Mean age (SD), y	60 (9.6)	60 (9.6)	.9
Men, %	89	91	.9
Married, %	88	88	1.0
Educational level, %			.7
Less than high school	28	31	
High school graduate	24	18	
Some college	16	17	
College graduate	32	34	
Income level, %			.4
< $40,000	39	39	
$40,000 to $60,000	12	20	
> $60,000	39	37	
Unknown	9	4	
CCVS Angina Scale, %			.8
Class I	21	26	
Class II	45	47	
Class III	32	27	
Class IV	2	1	
No. of diseased arteries			.06
1	25	17	
2	26	19	
≥3	49	64	
Left ventricular function, %			.3
Grade I	50	62	
Grade II	40	28	
Grade III	7	9	
Grade IV	3	1	
Comorbitities present, %	17	23	.3
SF-36 scores, mean % (SD) (Minimum, median, maximum)			
General health	58 (19) (20, 62, 97)	58 (20) (20, 58, 95)	.8
Physical functioning	61 (25) (5, 65, 95)	60 (25) (10, 65, 100)	.6
Role functioning	43 (41) (0, 25, 100)	42 (41) (0, 25, 100)	.3
Bodily pain	72 (24) (21, 82, 100)	75 (24) (0, 82, 100)	.3

of treatment decisions was also performed at 6 months for those with 3 or more diseased coronary arteries compared with those with less than 3 diseased coronary arteries. Revascularization rates for those with 3 or more diseased vessels were 67% in the control group and 57% in the intervention group, compared with 65% and 43% of those with less than 3 diseased vessels in the control and intervention groups, respectively. The difference in these differences in proportions was not significantly different from zero ($P = .45$ by logistic regression).

Table 2. Mean Satisfaction and Knowledge Scores

Outcome	Control Group *n* = 97	SDP Group *n* = 90	Delta	95% Confidence Interval Around Delta	*P* Value
Satisfaction*	70%	71%	1%	(−3%, 7%)	.5
Knowledge*	62%	75%	13%	(+8%, 18%)	<.001

**Satisfaction was measured using the 12-item Decision-Making Process Questionnaire,[19] and knowledge was measuring using a multiple item knowledge questionnaire (see Appendix 1 and 2).*

"Delta" is the difference between the mean score of the intervention group and control group.

Table 3. Initial Patient Treatment Decision and Actual Treatment at 6 Months

Outcome	Control Group	SDP Group	Delta	95% Confidence Interval Around Delta	*P* Value
Revascularization initial decision	75% (n = 97)	58% (n = 90)	17%	(4%, 31%)	.01
Actually performed by 6 months	66% (n = 95)	52% (n = 86)	14%	(0%, 28%)	.06

DISCUSSION

In this randomized trial, we hypothesized that the IHD SDP would assist in the shared decision-making process. The primary outcome of patient satisfaction with the decision-making process at the time of treatment decision revealed reasonably high satisfactions scores, with no difference between the control and intervention groups (Table 2). In two other reported randomized trials of SDPs, patients' satisfaction with the decision-making process was also found to be reasonably high.[19,21] In the first study, men with BPH were found to have a mean score for patients' satisfaction with the decision-making process of 76% when exposed to the interactive videodisc, compared with 71% for the control group at 3 months (P = .03).[19] The clinical significance of this 5% improvement is uncertain and is within the 95% confidence interval of our results. In the second study, IHD patients in the intervention group were exposed to a noninteractive, linear version (videotape) of the IHD SDP. The mean score for satisfaction with the decision-making process was 75% in both groups.[21]

Evidence that the IHD SDP assists in the decision-making process is provided by the increase in knowledge. In this study, SDP patients scored significantly higher than controls on the multi-item knowledge scale, with mean scores of 75% and 62%, respectively (Table 2). This scale was administered at least 1 month after viewing the IHD SDP at the time of the actual treatment decision. Patients in the IHD SDP group apparently learned more than the controls and retained this knowledge throughout the decision-making process. This observation is consistent with other reported results.[19–21] 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 to improve the informed consent process.

In this trial, fewer SDP patients indicated that they had chosen revascularization when compared with the control patients (Table 3). This observation represented what patients stated they had chosen and did not necessarily indicate the actual treatment performed. However, results at 6 months revealed that revascularization rates in the intervention group remained lower than in the control group (Table 3). However, the 95% confidence interval for the true difference ranged from 0% to 28%. Despite this possible reduction in aggressive therapy in the intervention group, outcome scores, including SF-36 and angina scores, at 6 months were comparable to the control group (Table 4).

An additional observation was that exposure to the IHD SDP appeared to result in more disagreement between the patients and angiographers about the preferred treatment (Table 5). Yet SDP patients were as likely to report that the treatment decision was a shared one, and they appeared as satisfied as the controls (Table 2). This may suggest that decision aids such as the IHD SDP have a significant role to play in promoting shared decision

Table 4. Angina and SF-36 Scores at 6 Months

	Control Group n = 88	SDP Group n = 72	*P* Value
CCVS Angina Scale, %			.8
None	48%	49%	
Class I	27%	25%	
Class II	19%	24%	
Class III	4%	1%	
Class IV	2%	1%	
SF-36 scores, mean % (SD) (Minimum, median, maximum)			
General health	65 (20)	62 (23)	.8
	25, 67, 100	10, 67, 100	
Physical functioning	71 (24)	67 (29)	.6
	15, 80, 100	0, 77, 100	
Role functioning	58 (43)	62 (44)	.3
	0, 75, 100	0, 100, 100	
Bodily pain	77 (24)	81 (21)	.3
	12, 82, 100	34, 85, 100	

Table 5. Patient Preference for Treatment Given Angiographer's Recommendation

Angiographer Recommendation	Group (*n*)	Number of Patients that Agreed (%)	Fisher Test *P* Value
Medical therapy alone	SDP (11)	10 (91)	.32
	Control (12)	8 (67)	
Revascularization	SDP (69)	45 (65)	.01
	Control (71)	60 (84)	

For the interaction of intervention group and angiographer's recommendation from the logistic regression model, P = *.02. The analysis does not include 10 cases in the SDP group and 14 cases in the control group where no recommendation was given.*

making by assisting patients in clarifying and expressing values and preferences even when their physicians have different values and preferences.

The acceptability of the IHD SDP may vary depending on the method of health care delivery. In Canada, the diagnostic coronary angiogram often precedes angioplasty, allowing the patient and family the opportunity to view the IHD SDP and assess therapeutic options. In the United States, these two procedures are often performed at the same time, making exposure to the IHD SDP difficult. Further research is needed to evaluate the use of modified SDPs that can be incorporated into these two methods of health care delivery.

Our sample size requirement of 84 per group was met, despite the entry drop-out rate of 22%. Furthermore, only a slightly higher drop-out rate was seen in the SDP arm, compared with the control arm (28% vs 22%, respectively), even though the IHD SDP arm required an extra visit to view the IHD SDP. The drop-out group reported lower incomes, lower general health and physical functioning scores, and higher bodily pain scores ($P \leq .05$). This may have affected our results, since it has been reported that patients with less education may benefit the most from the IHD SDP.[20] Selection bias was minimized by enrolling available consecutive eligible patients. Of the 279 eligible patients, 240 consented and were enrolled in the study.

The satisfaction with decision-making scale was chosen as the primary outcome. This scale has been shown to be reliable and valid in men who were facing treatment decisions about BPH.[19] Arguably, 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 scale in this "high risk" treatment decision may have been different than in the "low risk" BPH scenario. Further research evaluating the performance of satisfaction scales in low and high risk decision making is warranted.

A theoretical risk to the internal validity was contamination, the possibility that the control group was exposed to the 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 and is therefore difficult to duplicate. Second, there was a large number of cardiologists and cardiovascular surgeons involved, and the probability of a significant number of them changing their practice behavior during the duration of this trial is low. A secondary analysis of the primary outcome stratified by angiographer gave the same results as the unstratified analysis. The absence of blinding may also have affected 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, and standardized baseline and decision questionnaires were completed for 187 of the 240 patients enrolled.

Issues of generalizability include the lack of women in this trial (Table 1). The main reason for this was not because women refused to participate, but 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 others who have shown that women undergo coronary angiography at lower rates than men and that other gender-based differences exist in the diagnostic work-up of ischemic heart disease.[26,27] The study population was limited to English-speaking 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. Furthermore, for SDPs to remain accurate, they must be updated as new information important to decision making is acquired. For example, the IHD SDP does not discuss the treatment option of coronary artery stenting in depth, a procedure that has become an important option in revascularization. As a medium, interactive videodisc technology is expensive to develop and implement effectively into health care delivery systems. Other more convenient media, such as VHS video, CD-ROMs, and the World Wide Web, must be utilized if decision aids are to become a widely used adjunct to patient-physician decision making.

In this prospective, randomized trial, we found that patients exposed to the IHD SDP were reasonably satisfied with the decision-making process. However, there was no significant difference in the primary outcome

(with relatively tight confidence intervals) when compared with usual practice. The secondary outcomes revealed that IHD SDP patients were more knowledgeable, underwent less revascularization (interventional therapies), and demonstrated increased patient decision-making autonomy without apparent impact on quality of life or clinical outcomes. These observations give the impression that decision aids like the IHD SDP do have possible desirable effects. This sets the stage for further research in the area of improving health care value through shared decision making.

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APPENDIX 1

Satisfaction with Decision Making Questionnaire

1. I got as much information as I wanted about my heart condition.
2. I am satisfied that I was adequately informed about the different treatments available for my heart condition.
3. I had as much input as I wanted in the choice of treatments for my heart condition.
4. I am satisfied that my own opinion was important in the decision about treatment for my heart condition.
5. Looking back, I think I relied too much on the opinion of my doctors in deciding which treatment to choose.
6. How would you rate the explanations of medical procedures and tests for your heart condition?
7. How would you rate the personal interest in you and your medical problems by your doctors and staff?
8. How would you rate the reassurance and support offered to you by your doctors and staff?
9. How would you rate the amount of time you had with your doctors and staff during visits?
10. How would you rate the amount of help you got dealing with your heart condition?
11. How would you rate the amount of information you got about your heart condition and its treatments?
12. How would you rate the attention given to what you had to say about your heart condition?

Response frame for questions 1 to 5

1. Strongly Agree 2. Agree 3. Neither Agree nor Disagree 4. Disagree 5. Strongly Disagree.

Response frame for question 6 to 12

1. Excellent 2. Very Good 3. Good 4. fair 5. Poor

APPENDIX 2

Knowledge Questionnaire

1. Coronary artery disease is cause by plaques (deposits) that block the blood vessels which surround and supply the heart muscle (the coronary arteries).
2. Coronary artery disease does not cause serious complications such as heart attack or death.
3. Coronary artery disease itself can be cured by a number of treatments including angioplasty and bypass surgery.
4. Most patients who choose ongoing medical therapy alone are often able to discontinue their medication after a few years.
5. Medical therapy is almost always successful in completely relieving angina.
6. By choosing medical therapy now, a person will be unable to have either bypass surgery or angioplasty in the future.
7. Possible side effects from medical therapy include fatigue, headache, decreased concentration, and sexual dysfunction.
8. During surgery the blocked coronary arteries are bypassed, commonly using blood vessels from the leg and chest.
9. Most patients who undergo bypass surgery are hospitalized for fewer than 5 days.
10. Each treatment option carries with it some risk of stroke, heart attack, or death.
11. After bypass surgery or antioplasty. "lifestyle" changes (e.g., diet, smoking cessation, regular exercise) are not as important as when medical therapy is used.
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.
13. When compared with medical therapy, bypass surgery has a higher risk of immediate complications (such as heart attack, stroke, or death).
14. Bleeding requiring a blood transfusion may occur with bypass surgery.
15. After bypass surgery, some patients experience difficulty concentrating and some memory loss, which usually resolves.
16. Angioplasty is similar to an angiogram, but is a more complicated procedure which involves inflating a balloon to open up a blocked artery.
17. If angioplasy "works" and the patient has no angina 1 month later, this means that it is unlikely that the angina will ever return.
18. When compared with medical therapy, angioplasty has a higher risk of immediate complications (such as heart attack, stroke, or death).
19. Some angioplasty patients may require repeat angioplasty or even bypass surgery in the future.
20. Occasionally an artery can be damaged during angioplasty and emergency bypass surgery is required.

Response frame for questions 1 to 20

1. True 2. False 3. Don't know

**Reduced to 15 items if angioplasty is not an option.*