

# A randomized controlled trial of information-giving to patients referred for coronary angiography: effects on outcomes of care

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## Abstract

**Objective** To assess the impact of providing an educational videotape, 'Treatment Choices for Ischaemic Heart Disease: a Shared Decision-Making Program Videotape,' to patients referred for coronary angiography compared with standard patient-physician decision making (usual care).

**Study design** Randomized controlled clinical trial.

**Setting** University Hospital and Veterans Affairs Hospital.

**Patients** A consecutive sample of 217 patients referred for coronary angiography were randomized to receive 'usual care' or to receive the videotape in addition to standard patient physician decision making (videotape): 109 completed the study (50% completion rate).

**Main outcome measures** Knowledge of coronary artery disease, satisfaction, self-reported physical and mental health functioning, and the proportion of patients who were referred for coronary revascularization.

**Results** Compared with patients who received 'usual care,' those who received the videotape were more knowledgeable (mean score 83 vs. 58%;  $P < 0.0001$ ) but less satisfied with their treatment (79 vs. 88%;  $P = 0.038$ ). There were no significant differences between the videotape and 'usual care' groups with respect to satisfaction with the decision making process (mean score 73 vs. 77%;  $P = 0.37$ ), satisfaction with the decision made (mean score 73 vs. 78%;  $P = 0.28$ ), physical functioning (38 vs. 38%;  $P = 0.76$ ), mental health functioning (49 vs. 49%;  $P = 0.94$ ), or in referral for coronary revascularization (OR 0.60; 95% CI 0.22–1.65;  $P = 0.33$ ).

**Conclusion** Although the educational videotape increased patients' knowledge level, it was associated with a decrease in their level of satisfaction with treatment. Before there is wide-spread dissemination of this technology, advocates should demonstrate its effectiveness in everyday practice.

## Introduction

Cardiovascular disease is the leading cause of death in the world.<sup>1</sup> Perhaps because there are a large number of diagnostic and therapeutic options available for patients with coronary artery disease, there are wide variations in their clinical management. For example, patients who are either newly diagnosed with ischaemic heart disease or are experiencing a change in symptoms must choose, with their physician, between medical therapy, percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG) surgery. Patients should ideally make their decision after diagnostic coronary angiography has clearly identified the extent of their coronary artery disease, based on their own values for, or preferences about, their current health condition as well as possible outcomes of different treatment options. Therefore, it is important to provide patients with information on the various treatment options and potential outcomes of those decisions in a timely manner.

One proposed method is called the Shared Decision-making Program (SDP) and consists of either an interactive multimedia computer programme or a videotape.<sup>2</sup> Unfortunately, the ischaemic heart disease computerized programme requires detailed information on the severity of the patient's coronary artery disease and left ventricular function. Although this permits calculation of patient specific outcomes, it does not reflect the current practice in the United States where many patients referred for elective coronary angiography are asked for their approval to undergo PTCA prior to delineation of their coronary artery disease at catheterization. If coronary artery disease amenable to PTCA is found on coronary angiography, many of these patients then immediately undergo PTCA.

The videotape version of this same material, however, can be provided to patients prior to coronary angiography. Although some of these patients will not have significant disease and others will have severe disease, we believe this is the only feasible time to educate many of these

patients about ischaemic heart disease and their treatment choices. Patients would then be better informed healthcare consumers.

To determine the effect of providing such an educational videotape to patients referred for coronary angiography, we conducted a randomized controlled trial. Our primary objectives were to determine whether patients who viewed the videotape were more satisfied with the decision making process, the decision made, and their treatment than patients who received standard physician counselling. Our secondary objectives were to determine the impact of the videotape on the patient's knowledge of coronary artery disease, treatment decision, and health status.

## Methods

### Setting and patient selection

The study was conducted at the University of Michigan Hospital and the Ann Arbor Veterans Affairs (VA) Hospital. Patients referred for outpatient diagnostic coronary angiography were eligible to be enrolled in the study. Exclusion criteria included: (1) history of CABG, intracoronary stent, severe valvular heart disease, heart transplant, or congenital heart disease; (2) referral for a right-heart catheterization or coronary intervention; (3) history of myocardial infarction within 3 weeks; (4) pregnancy; (5) difficulty understanding English; and (6) hearing, vision, or cognitive impairment. Patient enrolment began in September 1996 at the Veterans Affairs Hospital (VA) and in November 1996 at the University Hospital. Enrolment was closed in May 1997 for both hospitals.

All but one of the cardiologists referring patients for diagnostic coronary angiography gave permission for the research team to approach their eligible patients for the study. Patients referred for coronary angiography were initially assessed for eligibility by their referring physician at the University Hospital and by Cardiology Research Nurses at the VA Hospital. In order to maximize timely contact with referring physicians at the University Hospital, one of

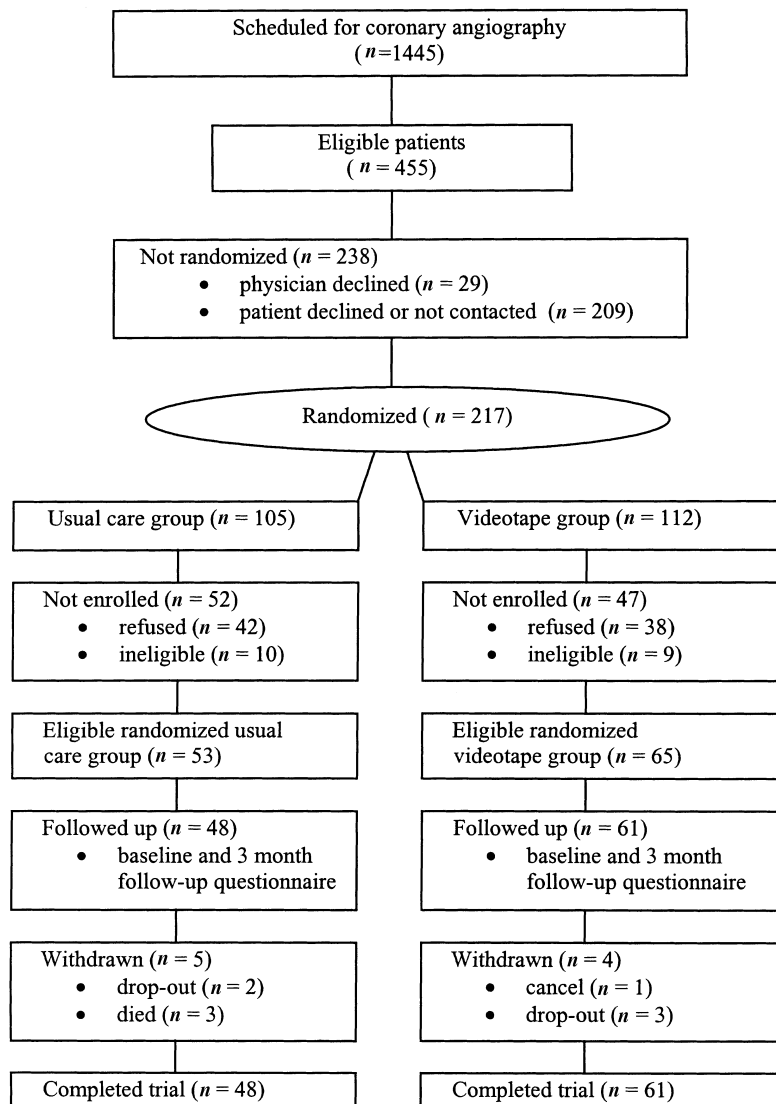
the authors (SJB) received permission to screen all University patients referred for eligibility.

The study was approved by the two hospitals' institutional human subject protection committees.

### Study design

University patients were usually contacted within 2 days of being scheduled for coronary and angiography and VA patients were notified of the study at the time they were scheduled for their procedure. Those eligible patients who agreed to consider participating were then ran-

domized to standard patient-physician decision making (i.e. the 'usual care' or control arm) or to receive a 54-minute educational videotape, 'Treatment Choices for Ischaemic Heart Disease: a Shared Decision Making Program Videotape,' prepared by the Foundation for Informed Medical Decision Making (i.e. the 'videotape' or intervention arm) as shown in Fig. 1. Randomization was performed by a study coordinator opening opaque, sealed envelopes at study headquarters. Randomization was stratified by study site in concealed blocks of 10. Neither subjects nor study staff were blinded to treatment assignment.



**Figure 1** Profile of patient recruitment into study.

Patients in both arms were express mailed a self-administered baseline questionnaire and an informed consent form. A written informed consent form was required for participation in the study. Patients in the intervention arm also were sent the videotape with the baseline questionnaire. The videotape provided information on the benefits and risks of medical therapy, PTCA and CABG; what a patient could expect to happen if they chose each of these options; and information on lifestyle changes that might benefit the patient. Patients were to return their forms by mailing them in a pre-addressed, postage-paid envelope or to bring the forms with them to their coronary angiography appointment.

Three months after the patients had undergone coronary angiography, they were mailed a self-administered follow-up questionnaire. Patients who did not return their questionnaires were contacted by telephone and a repeat questionnaire was mailed or the form was completed over the phone.

Medical record data were abstracted by two trained physician reviewers. Abstractors were trained regarding terminology, specific types of test reports they might encounter, coding procedures, and abstracted sample cases. Chart review included the coronary angiography report, discharge summaries, and referral letters. Data were directly entered into computer files.

#### Patient sample

A total of 1445 consecutive patients were scheduled to undergo coronary angiograms during the enrolment period (see Fig. 1). Of those, 990 patients met exclusion criteria and 238 patients declined to participate or could not be contacted. The remaining 217 patients were contacted by telephone and agreed to consider participating in the study. They were then randomized to the control ( $n = 105$ ) or intervention ( $n = 112$ ) arm per the study protocol. Ninety-nine of these patients were not formally enrolled in the study because they either declined to participate ( $n = 80$ ) or were found to be ineligible for the study on review of their medical records

( $n = 19$ ). There were 118 eligible randomized patients (53 in the usual care group and 65 in the videotape group) who completed the informed consent form and baseline questionnaires. Nine patients failed to complete the follow-up questionnaire: five patients in the Usual Care group (two dropped out and three died) and four patients in the videotape group (three dropped out and in one case the coronary angiogram was cancelled). The final study group consisted of 109 patients who completed both the baseline and follow-up questionnaires as required by the study design (50% of original randomized population and 92% of the eligible randomized patients): 48 patients were in the control arm and 61 in the intervention arm.

#### Baseline questionnaire

The baseline questionnaire collected socio-demographic information (e.g. age, race, gender, educational level, marital status, income and health insurance status), general health information, and information about their preference for PCTA or CABG if coronary revascularization was recommended. To control for the patient's health at time of entry into the study, we assessed their health status with two previously validated instruments: (1) the Medical Outcomes Study SF-12, a 12-item generic measure of health status; and (2) the Seattle Angina Questionnaire (SAQ), a 19-item cardiac specific measure of health. The SF-12 can be used to calculate a Physical Component Summary Score (PCS) and a Mental Component Summary Score (MCS).<sup>3</sup> The test-retest reliability of these scales were 0.89 and 0.76, respectively.<sup>4</sup> The SAQ was used to assess five dimensions of coronary artery disease: physical limitation (nine items), anginal frequency (two items), treatment satisfaction (four items), disease perception (three items) and anginal stability (one item).<sup>5,6</sup> The Cronbach's alpha for the first four dimensions, as measured in our study, were 0.92, 0.74, 0.83 and 0.68, respectively. The fifth dimension was assessed with a single item question. Scores were standardized to a 0–100 scale with higher values reflecting better health.

We also assessed other factors that might influence the patient's response to the intervention. To assess the patient's desire to make decisions and desire to be informed, we used six and eight items, respectively, from the previously validated 23-item scale developed by Ende *et al.*<sup>7</sup> The Cronbach's alpha was 0.73 for the Desire to Make Decision scale and 0.84 for the Information Seeking scale in this study. We also assessed whether patients preferred to defer their decision to their provider and if they wanted to carefully deliberate their options using a 3-item Deferrer scale (alpha = 0.66) and 4-item Deliberator scale (alpha = 0.87) developed by Pierce *et al.* (Pierce, personal communication.) To measure the degree of certainty our patients had regarding their potential decision, we used a 3-item Decision Certainty scale developed by O'Connor which has previously been demonstrated to be reliable, valid and responsive.<sup>8</sup> The Cronbach's alpha was 0.77 in this study. All scores were standardized to a 0–100 scale with higher scores reflecting a stronger desire to make decisions, seek information, make their own decision, deliberate their options, and be more certain about their decision, respectively.

#### Knowledge questionnaire

Knowledge about coronary artery disease and its treatment was assessed prior to coronary angiography with a 20-item multiple choice test developed by Morgan *et al.* which has been shown to have criterion validity.<sup>9</sup> Response categories were true, false and uncertain. One question was deleted from our final analysis (i.e. 'most patients who undergo bypass surgery are hospitalized for fewer than 5 days') as the answer might vary between our VA and University patients. Each correct response received one point and scores were standardized to a 0–100 scale with higher values reflecting greater knowledge. The Cronbach's alpha in this study was 0.86. For patients who were randomized to the videotape group, we assessed knowledge following viewing of the videotape. This was designed to see if patients who viewed the videotape were

more knowledgeable than patients who received standard physician counselling.

#### Follow-up questionnaire

The patient's health status was assessed with the Medical Outcomes Study SF-12 and the Seattle Angina Questionnaire. Since the goal of the study was to determine if the videotape improved the patient's satisfaction, we used three previously developed scales. To assess the patient's satisfaction with the decision making process, we used a 12-item validated scale developed by Barry *et al.* for patients considering treatment choices for benign prostatic hypertrophy.<sup>10</sup> In this study the Cronbach's alpha was 0.94. To assess the patient's satisfaction with the decision made, we used a three-item validated scale developed by Barry *et al.*<sup>10</sup> The Cronbach's alpha in this study was 0.81. Both sets of questions were modified to reflect the decisions facing patients with ischaemic heart disease. Finally, we used the satisfaction with treatment subscale from the SAQ to reflect satisfaction with current treatment. All scores were standardized to a 0–100 scale with higher scores reflecting greater satisfaction.

#### Chart review

We collected the following data: severity of coronary artery disease, whether the patient was a candidate for PTCA or CABG, initial recommendation of treatment following coronary angiography and all cardiovascular treatments the patient underwent through 6 months follow-up. Double data entry was carried out for all data.

#### Sample size calculation

The sample size for this study was calculated based on our primary outcomes: (1) satisfaction with the decision making process and (2) satisfaction with the decision made. Based on the work of Barry *et al.* we assumed that the standard deviation would be 16 and that a

difference of half a standard deviation would be clinically significant.<sup>10</sup> A sample size of 63 per arm would give us an 80% power to detect a half a standard deviation between groups with an alpha of 0.05 using a two-tailed test.

### Statistical analysis

Baseline variables were compared between the control and intervention arms using the *t*-test for continuous variables and chi-square for categorical variables. ANOVA was used to compare post-intervention scores from the MOS SF-12 and the SAQ sub-scales between groups while controlling for baseline health status. ANOVA was also used to compare treatment satisfaction levels between groups at follow-up while controlling for baseline treatment satisfaction. To assess whether there was a difference in knowledge levels, satisfaction with the decision making process, and satisfaction with the decision made, we used *t*-tests.

Logistic regression analysis was used to evaluate the impact of selected explanatory factors on the referral for coronary revascularization. We initially performed simple univariate analyses with the dependent variable being referral for coronary revascularization and the independent variables being selected explanatory factors (e.g. randomization group, age, gender, coronary artery disease). We then performed multivariate logistic regression to examine the effect of randomization group while controlling for potential confounders. For all statistical tests, a value of  $P < 0.05$  was considered statistically significant. All computer analyses were performed with the STATA 5.0 statistical programme.

## Results

### Sample characteristics

There were 109 patients who completed both baseline and follow-up questionnaires, 48 in the control arm and 61 in the intervention arm. Seventy-nine *per cent* of the patients were male, 86% were white, their mean age was 60.6 years and their age range was 35–80 years (see

Table 1). The control group tended to be older, less educated, and with lower perceived health status than the videotape group. There were no differences between groups with respect to insurance, income, marital status or history of heart attack. The groups differed in various indicators of disease severity and in treatment preferences, although these differences were not considered statistically significant. Prior to coronary angiography, patients more strongly preferred PTCA to CABG if they were found to have coronary artery disease (59 vs. 9%,  $P < 0.001$ ).

There were no significant differences between patients who dropped out of the study following randomization and those who completed it with respect to age (61.9 vs. 60.6 years;  $P = 0.34$ ), percentage of male patients (79% vs. 94%;  $P = 0.06$ ), and severity of coronary artery disease ( $P = 0.11$ ).

### Baseline attitudinal measures

There was a strong desire for information among all patients (see Table 2). On the information seeking scale, the mean score was 86.6, where 100 refers to strong agreement with statements favouring patients being informed. Patients also wanted to consider their options carefully as indicated by the mean score of 83.6 using Pierce's Deliberator scale. There were lower scores on the desire to make decisions scale (mean score was 58.4) and the desire to defer decision making scale (mean score 55.3) indicating that patients wanted to share decision making with others. This is consistent with the findings of other studies where patients wish to have assistance with decision making.<sup>11</sup> Finally, prior to coronary angiography, patients had an average level of certainty (mean score 52.6) regarding the choices they would need to make following coronary angiography on O'Connor's decision certainty scale. The only difference between patients in the videotape arm and those who received standard physician counselling was that videotape patients had a mean score of 86.1 on Pierce's deliberator scale compared with a score of 80.2 for control patients ( $t = -2.38$ ;

**Table 1** Socio-demographic characteristics of coronary angiography patients

Characteristic	Total ( <i>n</i> = 109)	Control (standard counselling) ( <i>n</i> = 48)	Intervention (videotape) ( <i>n</i> = 61)	<i>P</i> -value
Age (mean, years)	60.6	61.9	59.4	0.21
Male gender (%)	79	81	77	0.63
Caucasian (%)	86	87	85	0.58
Post high school education (%)	55	49	60	0.25
Insurance (%)				0.95
Medicare	41	43	39	
Private	31	28	33	
Government	20	21	20	
Medicaid or none	8	9	8	
Income (% US\$)				0.88
< 20 000	47	47	47	
20 000–29 000	21	22	19	
≥ 30 000	32	31	34	
Marital status (% US\$)				0.91
Never married	5	4	5	
Married or common	67	70	67	
Separated or divorced	20	19	20	
Widowed	7	6	8	
Health status (%)				0.11
Excellent	3	0	5	
Very good	17	9	23	
Good	35	38	32	
Fair	33	36	30	
Poor	13	17	10	
Prior myocardial infarction (%)	35	35	35	0.98
Prior PTCA* (%)	18	15	21	0.52
Coronary anatomy (%)				0.24
Left main/3 vessel	37	47	29	
1 or 2 vessel with PLAD involvement <sup>†</sup>	7	4	10	
1 or 2 vessel without PLAD involvement	32	30	33	
No disease or minor disease	24	19	28	
Revascularization preference (%)				0.24
Prefer CABG <sup>‡</sup>	9	15	5	
No preference	32	27	36	
Prefer PTCA	59	59	59	

\*PTCA – percutaneous transluminal coronary angioplasty, <sup>†</sup>PLAD – proximal left anterior descending coronary artery

<sup>‡</sup>CABG – coronary artery bypass graft surgery

*P* = 0.02) indicating a stronger preference to deliberate about their treatment decisions.

#### Baseline health related measures

On entry to the study, the patients had a low level of physical functioning (see Table 3) on the MOS Physical Component Summary Score

(mean score 35.7) compared with the general United States population (mean score 46.7).<sup>4</sup> In contrast, the patients' MCS of 48.8 indicated a level of mental functioning similar to that of the general population.<sup>4</sup> There were no differences between control and intervention arms on either of these two scales. On the more specific SAQ, we found that patients in the control arm tended

**Table 2** Comparison of baseline attitudes toward decision making, by group [all scales range from 0 to 100; all data mean (standard deviation)]

Measure	Total	Control (standard counselling)	Intervention (videotape)	<i>t</i> -value	<i>P</i> -value
Information seeking	86.6 (11.2)	85.0 (11.3)	87.8 (11.0)	-1.29	0.2
Desire to make decisions	58.4 (17.9)	59.1 (17.0)	57.9 (18.6)	0.34	0.7
Decisional certainty	52.6 (22.6)	53.9 (23.5)	51.7 (21.9)	0.46	0.6
Desire to deliberate decisions	83.6 (12.9)	80.2 (12.0)	86.1 (13.2)	-2.38	0.02
Desire to defer decision making	55.3 (10.7)	55.4 (9.1)	55.2 (11.9)	0.07	0.9

to have a lower level of physical functioning (56.6 vs. 64.5;  $t = -1.83$ ;  $P = 0.11$ ) compared with those in the intervention arm. There were no significant differences between groups with respect to the stability of their angina, anginal frequency, treatment satisfaction and disease perception on entry to the study.

#### Intervention effects on satisfaction

Overall, patients were reasonably satisfied with the decision making process and with the decision they made, with mean scores of approximately 75 for each group. Although there was a trend toward greater satisfaction levels among patients who received standard physician counselling compared with those who received the videotape, there were no significant differences. On the satisfaction with the decision making process scale, the standard counselling group's score was 76.5 while the videotape group's score was 73.1 ( $t = 0.89$ ;  $P = 0.37$ ); on the satisfac-

tion with the decision made scale, the scores were 77.7 and 73.1, respectively ( $t = 1.08$ ;  $P = 0.28$ ).

Treatment satisfaction increased significantly from baseline to follow-up for both the control ( $t = 3.00$ ;  $P = 0.005$ ) and intervention arms ( $t = 2.32$ ;  $P = 0.024$ ) on the SAQ treatment satisfaction scale (see Table 3). In addition, patients who received standard physician counselling were significantly more satisfied with their treatment at follow-up than those in videotape group (88.3 vs. 78.8;  $F = 4.47$ ;  $P = 0.038$ ) even after controlling for baseline satisfaction, severity of coronary artery disease, gender, education, and treatment decision.

None of the patient's baseline attitudes toward information seeking, desire to be involved in decision making, desire to defer decisions, desire to deliberate about decisions, nor their decisional certainty, were predictive of their final satisfaction with treatment on any of these scales.

**Table 3** Baseline and post-intervention health related measures, by group [all scales range from 0 to 100, all data mean (standard deviation)]

Instrument	Baseline			Follow-up		
	Control	Intervention	<i>p</i> -value	Control	Intervention	<i>P</i> -value
Medical outcomes study SF-12						
Physical functioning	33.8 (11.3)	37.4 (12.7)	ns	37.6 (10.6)	38.0 (12.1)	ns
Mental health functioning	48.0 (10.9)	49.1 (12.6)	ns	48.9 (10.8)	49.1 (11.4)	ns
Seattle Angina Questionnaire						
Treatment satisfaction	77.8 (22.7)	72.6 (22.2)	ns	88.3 (13.9)	78.8 (24.1)	0.016
Anginal stability	43.9	49.2	ns	72.2	66.4	ns
Anginal frequency	67.4 (24.3)	69.1 (28.2)	ns	82.7 (20.5)	74.6 (29.0)	
Disease perception	51.6 (23.8)	47.2 (26.1)	ns	70.4 (23.3)	61.3 (28.3)	ns
Physical capacity	56.6 (22.7)	64.5 (25.4)	0.11	63.7 (29.0)	64.0 (31.0)	ns



### Intervention effect on knowledge

Patients in the intervention arm knew significantly more about ischaemic heart disease and its treatment than those in the control arm (83.0 vs. 57.9;  $t = -8.16$ ;  $P < 0.0001$ ). The patients in the intervention arm also had less uncertainty. Videotape patients were only uncertain about 5% of the questions compared with the control group who were uncertain about 32% of the questions.

### Intervention effects on health related measures

At follow-up, there were significant improvements for patients in both the control and intervention arms, compared with baseline, in anginal stability ( $P < 0.001$  for both groups), anginal frequency ( $P = 0.002$  and  $0.014$ , respectively), and disease perception ( $P = 0.0001$  for both groups). Control patients also had better physical capacity ( $P = 0.039$ ) at follow-up compared with baseline. However, there was no significant effect of the intervention on the patient's health as measured by the MOSPCS or MCS nor by the SAQ's physical capacity, anginal stability, anginal frequency, and disease perception subscales.

### Intervention effects on the referral process

Forty-one per cent of the videotape group underwent coronary revascularization compared with 58% of the control group (OR 0.50; 95% CI 0.23–1.07;  $P = 0.07$ ). Since the patients in the control and intervention arms differed on some clinical factors that could influence a physician's decision to refer patients for coronary revascularization, we first examined these factors in a univariate analysis (see Table 4). We then examined a multivariate model, controlling for randomization group and each of the other factors found to be significant on univariate analysis, and found that there were only two significant predictors of referral for revascularization: (1) severity of coronary artery disease – patients with left main or three vessel disease were more likely to be referred for revascularization compared with those with one or two vessel disease not involving the proximal left anterior descending artery (OR 24.9; 95% CI: 6.4–97.9;  $P < 0.001$ ); and (2) educational level – patients with 12 or fewer years of education were more likely to undergo coronary revascularization than those with a

**Table 4** Referral for coronary revascularization by clinical or sociodemographic characteristic

Characteristic	Univariate analysis			Multivariate analysis		
	Odds ratio	95% CI	<i>P</i> -value	Odds ratio	95% CI	<i>P</i> -value
Male	4.55	1.5–13.4	0.006	2.7	0.55–13.0	0.23
Age (years)						
< 55	–	–	–	–	–	–
55–64	3.69	1.30–10.5	0.014	2.42	0.60–9.68	0.21
≥ 65	1.77	0.72–4.31	0.21	0.35	0.09–1.42	0.15
Coronary artery disease						
1 or 2 vessel without PLAD involvement*	–	–	–	–	–	–
1 or 2 vessel with PLAD involvement	1.27	0.27–5.92	0.76	2.59	0.41–21.5	0.27
Left main or 3 vessel	6.15	2.14–17.7	0.001	24.9	6.4–97.9	0.000
Stress test (positive)	2.63	0.98–7.03	0.054	3.08	0.71–13.3	0.13
Site (University)	0.45	0.22–0.98	0.044	0.98	0.24–3.90	0.98
Group (experimental)	0.50	0.23–1.07	0.074	0.72	0.24–2.09	0.54
Education (≤ high school)	3.14	1.43–6.95	0.004	3.4	1.08–10.78	0.036
History of myocardial infarction	1.90	0.85–4.30	0.12	0.86	0.25–3.01	0.82
History of PTCA <sup>†</sup>	1.58	0.58–4.29	0.37	1.20	0.28–5.28	0.80

\*PLAD – proximal left anterior descending coronary artery, <sup>†</sup>PTCA – percutaneous transluminal coronary angioplasty, ‡ ns – non-significant

higher level of education (OR 3.4; 95% CI: 1.08–10.78;  $P = 0.036$ ). There was no significant difference in the odds of a videotape patient undergoing revascularization compared with a control patient (OR 0.60; 95% CI: 0.22–1.65;  $P = 0.33$ ).

## Discussion

This randomized controlled trial was designed to determine the effect of providing an educational videotape to patients referred for coronary angiography. We found that there were no differences between patients who received the videotape and those who received standard physician counselling with respect to satisfaction with the decision making process, satisfaction with the decision made or treatment choice. However, patients who were in the videotape group were more knowledgeable about ischaemic heart disease and less satisfied with their treatment than control patients.

These findings are similar to those reported by Morgan *et al.* in their randomized controlled trial of the computerized version of the Shared Decision-Making Program for ischaemic heart disease in 180 Canadian patients following coronary angiography.<sup>9</sup> They also found no significant differences in the mean satisfaction with decision making process nor in the satisfaction with decision made scores between their intervention and control groups.<sup>9</sup> However, in a trial conducted in patients with benign prostatic hypertrophy, Barry *et al.* reported that patients who used the SDP were more satisfied with the decision making process than those in the control group, although there was no difference for satisfaction with the decision made.<sup>10</sup> This may reflect a difference in the types of decisions facing patients with ischaemic heart disease compared with those with benign prostatic hyperplasia.

We were not surprised by the lack of influence on the treatment decision for several reasons. First, we did not believe that an educational intervention such as the one used in this study would be sufficient to change practice patterns. Second, we had limited power to detect such an

effect since only 82 of the 109 patients had coronary artery disease where there would be a choice of treatment. Third, although observational studies had shown a reduction in prostatectomy rates for regions where patients used the computerized version of the SDP compared with control regions,<sup>12</sup> two randomized controlled found no significant effect on treatment.<sup>9,10</sup>

Similarly, the increase in patient knowledge was expected as we tested patient knowledge shortly after they viewed the videotape and because other studies had found that patients were more knowledgeable as long as four weeks after using the SDP programme.<sup>8</sup>

However, the lower SAQ treatment satisfaction score for the videotape patients was not expected. One possible explanation for the different results between the SAQ satisfaction with treatment scale and the satisfaction with decision-making process and decision-made scales is that increased knowledge may be associated with greater anxiety among some patients who use the SDP<sup>13</sup> and this may lead to lower satisfaction with overall treatment but not with a specific decision. In addition, the SAQ satisfaction with treatment scale examines current satisfaction levels, while the satisfaction with decision scale measures satisfaction levels retrospectively at the time the decision was made approximately 3 months earlier.

There are several limitations to this study. First, we had fewer patients than our original sample size estimates due to the large number of patients who declined to participate or who were found ineligible following randomization. Given the differences we found between groups, this is important when considering our finding of lower coronary revascularization referral rates for videotape patients. Our study only had a power of 0.40 to detect a difference of this magnitude and thus there may have been a significant effect on referral rates. A larger study is required to address this interesting possibility. Second, despite this being a randomized controlled trial, our control and experimental groups differed slightly on several clinical variables that could influence the decision to undergo coronary

revascularization. It is also possible that responses to some baseline variables might have been influenced by the viewing of the video prior to filling in the baseline questionnaire, as the baseline questionnaire was despatched in the same package as the video. Third, the SDP was designed to be used by patients with coronary artery disease amenable to treatment with either PTCA, CABG or medical therapy. Yet, in this study, we provided it to patients prior to coronary angiography. Thus, although the videotape may have had the desired effect on this subgroup of patients, the effect may have been diluted by patients with more or less coronary artery disease. We did this because of the current practice patterns for cardiovascular care in the United States. Although there may be sufficient delays in the referral process from coronary angiography to revascularization for Canadian chronic stable angina patients<sup>14</sup> to allow education to occur following coronary angiography, this is not always the case in the United States. In this study, the median waiting time from coronary angiography to angioplasty was 0 days for patients treated at the University Hospital and 13 days for those treated at the VA, however, even for VA patients, the decision on whether to refer the patient for PTCA was made for the majority of patients during the coronary angiography session.

Our findings of a limited impact of the SDP programme raise questions as to its effectiveness. Although all studies of the SDP programme have shown an increase in patient knowledge, which is important for patients to provide 'informed' consent, the lack of effect on treatment decision and satisfaction with the decision making process and with the decision made are troubling. Further evaluation of the cost-effectiveness of this technology is required before there is wide-spread dissemination.

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