Perceptions of Benefit and Risk of Patients Undergoing First-time Elective Percutaneous Coronary Revascularization

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OBJECTIVE: To assess reasons why patients undergo elective percutaneous coronary revascularization (PCR), patient expectations of the benefits of PCR, and their understanding of the risks associated with PCR. We hypothesized that patients overestimate the benefits and underestimate the risks associated with PCR.

DESIGN: A prospective, semistructured questionnaire.

PARTICIPANTS: Patients undergoing their first elective PCR.

MAIN RESULTS: Fifty-two consecutive patients with a mean age of 64.3 years (range 39-87) completed the interview. Although 30 (57%) patients cited relief of symptoms as at least 1 reason to have PCR, 32 (62%) patients cited either an abnormal diagnostic test result (i.e., exercise stress test or catheterization) or "pathophysiologic" problem (i.e., "I have a blockage"), with 17 patients (33%) citing these reasons alone as indications for PCR. Thirty-nine (75%) patients believed PCR would prevent a future myocardial infarction, and 37 (71%) patients felt PCR would prolong their life. Regarding the potential complications, only 24 patients (46%) could recall at least 1 possible complication. However, on a Deber questionnaire, the majority of patients (67%) stated that they should determine either mostly alone or equally with a physician how acceptable the risks of the procedure are for themselves.

CONCLUSIONS: The majority of patients had unrealistic expectations about the long-term benefits of elective PCR and was not aware of the potential risks, even though they expressed a strong interest in participating in the decision to have PCR. More work is needed to define the optimal strategy to educate patients about the benefits and risks of elec-

tive PCR, and whether such education will affect patient decision making.

KEY WORDS: decision-making; patient perceptions; percutaneous coronary revascularization; risk/benefit.

J GEN INTERN MED 2000;15:632-637.

The majority of percutaneous coronary revascularizations (PCR) performed each year in the United States are done electively for the palliation of symptoms in patients with coronary artery disease (CAD). Regional variation in the use of PCR for all types of coronary syndromes is notable in both the United States and other countries.^{1,2} For nonacute coronary syndromes, randomized trials have demonstrated that PCR is associated with better symptomatic relief when compared with medical therapy, but there is no definitive evidence to show that elective PCR is associated with lower mortality.³⁻⁷ Complications resulting from PCR can be serious and include arterial injury, stroke, myocardial infarction (MI), need for emergent coronary artery bypass grafting, and death.⁸ In the recently completed Randomised Intervention Treatment of Angina (RITA-2) trial, patients in the PCR group were almost twice as likely to experience either a non-fatal MI or death, compared with medically treated patients at a median follow-up of 2.7 years.^{3,9}

Although patient preference is the most important factor in medical decisions, patients need to make these decisions based on "informed" preferences with careful consideration of both benefit and risk. Previous studies of risk interpretation, using hypothetical scenarios, have demonstrated that individuals tend to overestimate small risks and underestimate large risks.¹⁰ However, little information is available about how actual patients perceive the balance of the benefits and risks for PCR. We hypothesize that patients underestimate risks while overestimating the benefits of elective PCR, even though they want a major role in the decision to undergo PCR. To address our hypothesis, we undertook this study to determine reasons why patients undergo elective PCR, patient expectations of the benefits of elective PCR for stable coronary artery disease, and patients' understanding of the risks associated with elective PCR. A secondary objective was to determine how much patients want to participate in the decision to undergo PCR.

METHODS

Study Sample

Consecutive patients scheduled for their first elective definite or possible percutaneous coronary revasculariza-

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The views represented by this paper are solely those of the authors and do not represent the views or opinions of the United States Navy or Department of Defense.

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tion at Yale-New Haven Hospital between September 15, 1997 and April 30, 1998 were eligible for the study. Patients with a prior history of PCR were excluded. Patients scheduled as "possible" PCR were all aware that they would receive PCR if deemed necessary by the cardiologist at the time of catheterization, and all patients were consented to undergo PCR. Patients were recruited from a university cardiology practice and 2 community-based practices. Patients were excluded if they were scheduled for primary or emergent PCR, were transferred from another hospital, were unable to give verbal consent (e.g., dementia), or did not speak English. There were no exclusions based on age or comorbidity.

Patient Interview

Patients were interviewed using a semistructured questionnaire by telephone the day before their scheduled procedure. The interview was conducted by 1 of 2 physicians (EH or DF) or a cardiac nurse practitioner (EC). The questionnaire addressed motivation to undergo PCR, expected impact of PCR on their symptoms, risk of mortality, and prevention of a future heart attack. A separate section inquired about the knowledge of the risks associated with PCR. All of these questions were asked in an open-ended format (see Appendix 1). Demographic and clinical characteristics obtained included age, gender, race, educational level, marital status, current medications, and use of tobacco.

Responses to the open-ended question "why are you having (either elective or possible) angioplasty" were first independently categorized by 2 investigators into a taxonomy of reasons based on a preliminary taxonomy developed from 8 pilot surveys. The final taxonomy was determined by consensus with a third investigator resolving differences. Patient responses could be classified in more than 1 category.

Other Data Collection

Patients were asked to complete a Seattle Angina Questionnaire (SAQ) the morning before their procedure. The SAQ is a validated instrument designed to measure 5 dimensions of functional status (physical limitation, anginal stability, anginal frequency, treatment satisfaction, and disease perception) in patients with coronary artery disease.¹¹ The range of possible scores on the SAQ is 0 to 100, with a higher score indicating fewer difficulties related to angina.

The morning following PCR, patients were interviewed by 1 of the 2 physician investigators in their room regarding their satisfaction with the procedure. They were asked to rate satisfaction on a 5-point scale, from 1 (highly dissatisfied) to 5 (highly satisfied). Charts were reviewed for complications and number and location of the treated coronary vessels. Finally, patients were also asked to complete the Deber Problem-Solving Decision-Making

Scale. This 6-item scale explores the role that patients wish to have in decisions about their care. The scale was designed to separate problem solving tasks from decision-making tasks and has been validated in patients with coronary artery disease.¹² The Yale University School of Medicine Human Investigation Committee approved the study.

Statistical Analysis

Reasons for undergoing PCR, patient assessment of specific benefits and risks, and responses to the Deber questionnaire are all presented as proportions. Mean scores for the SAQ were calculated using methods previously described.¹¹ Using Spearman correlation analysis, the associations between age, scores from the Deber questionnaire, and knowledge of complications were determined. Associations between the knowledge of complications, elective versus possible PCR, and physician group were also determined. The statistical analysis was performed using SAS version 6.12 (SAS Institute, Cary, NC).

RESULTS

Characteristics of Study Population

The participation rate was 87%. Five patients could not be contacted by phone the day before the procedure; one patient declined to participate. Two patients were called on the wrong day (day of procedure). The mean age was 64.3 years (range 39-87); the majority of patients were male, white, and married (Table 1).

Table 1. Demographic and Clinical Characteristics

Characteristic	Result
Number of study patients	52
Mean age, y (range)	64.3 (39-87)
Men, %	73
White, %	94
Married, %	77
Education completed, %*	
Less than high school	8
High school	46
College or greater	46
Current medications, %†	
Aspirin	88
Lipid-lowering drug	46
Nitroglycerin (any formulation)	36
β-blocker	68
Calcium-channel blocker	52
Number (%) scheduled for	
Elective PCR	32 (62)
Catheterization with possible PCR	20 (38)
Number (%) receiving PCR	44 (85)
Median number of vessels treated	1 (0-3)

*Four patients did not provide a response.

†Medications could not be determined for 2 patients.

Table 2. Reasons for Undergoing Percutaneous Coronary Revascularization

Category	Cited by any Patient n (%)	Only Reason Cited by Patient n (%)
Symptom relief	30 (57)	13 (25)
Abnormal test result or perception of pathology	32 (62)	17 (33)
Recommendation of physician	12 (19)	3 (6)

Of the 52 study patients, 44 patients received PCR. The number of vessels treated per patient ranged from 1 to 3, with the majority of patients receiving single-vessel PCR (Table 1). Every patient undergoing PCR received an intravascular stent as part of the procedure. Of the remaining 8 patients, all scheduled as outpatient catheterizations with possible angioplasty, 3 patients were referred for coronary bypass grafting surgery, and 4 were felt to have noncritical stenosis. One patient did not report for his procedure.

Anginal Symptoms and Functional Status

Forty-seven patients (90%) completed the SAQ; 1 (2%) patient did not show for his PCR, 2 (4%) did not complete enough items to score the SAQ, and 2 (4%) declined to fill out the SAQ. The mean score of 69 for the physical limitation subscale indicates that the majority of the 52 study patients were experiencing only mild limitations in physical activities.¹³ Seven patients (13%) reported having no symptoms.

Reasons for Undergoing PCR

When we classified the patients' reasons for undergoing the procedure, 3 categories emerged: (1) *recommendation* from a physician or other individual; (2) *diagnostic/pathophysiologic*, which included abnormal results on a diagnostic test (e.g., exercise stress test or catheterization) or perception of a pathophysiologic problem (e.g., "I have a blockage," or "The back of my heart is not getting enough blood flow"); and (3) *symptomatic*, which included symptoms the patient attributed to CAD (e.g., "I will have

no more chest pain and shortness of breath"). Patient responses could be categorized into more than 1 category.

The results are presented in Table 2. Thirty patients (57%) cited symptoms as at least 1 reason to undergo angioplasty, with 13 patients (25%) citing only symptoms as the reason for PCR. However, 32 patients (62%) cited a reason from the diagnostic/pathophysiologic category, with 17 patients (33%) citing only a diagnostic/pathophysiologic reason to undergo PCR. Three patients (6%) cited only a physician recommendation as the reason for having the procedure.

When asked directly about relief of symptoms, only 34 patients (65%) believed PCR would improve their symptoms, while 11 patients (21%) were uncertain about symptomatic improvement. In contrast, 39 (75%) and 37 (71%) patients, respectively, believed PCR would prevent a future MI or help them live longer.

Patients' Understanding of the Risks

Only 24 patients (46%) could state a possible complication of PCR when asked on the day prior to their procedure. The most frequently cited potential complications were stroke or MI, each cited by just 12 patients (23%), respectively. Only 20 patients (38%) were aware that the treated vessel could become "blocked" again (restenosis) after PCR. Thirteen patients (25%) spontaneously offered that they had not had any discussion concerning the risks of the procedure. Only 8 patients (15%) had signed a consent form at the time of the interview (day before their procedure). The majority of patients were consented (85%) the morning of the procedure by a cardiology fellow or nurse practitioner.

Table 3. Results of Problem-Solving and Decision-Making Scale*

Question	Patient Response n (%)				
	Physician Only	Mostly Physician	Physician and Patient Equally	Mostly Patient	Patient Only
Who should determine diagnosis?	20 (41)	19 (39)	9 (18)	0 (0)	1 (2)
Who should determine treatment options?	19 (49)	18 (37)	11 (22)	0 (0)	1 (2)
Who should determine risks and benefits?	20 (41)	15 (31)	9 (18)	1 (2)	4 (8)
Who should determine probability of risk/benefit?	26 (53)	16 (33)	5 (10)	2 (4)	0 (0)
Who should determine how acceptable risks/benefits are?	8 (16)	7 (14)	17 (35)	11 (22)	5 (10)
Who should determine which treatment is selected?	12 (24)	12 (24)	20 (41)	4 (8)	1 (2)

*The questionnaire was completed by 49 patients.

Patient Decision Making

The results from the Deber Problem-Solving Decision-Making scale are shown in Table 3. For problem-solving tasks, over 70% of all patients felt either only or mostly a physician should determine the diagnosis, treatment options, risks and benefits, and the probabilities of the risks and benefits. For decision-making tasks, while 67% felt that the acceptability of the risks and benefits should either be determined by themselves or equally with physicians, 49% still felt that the physician should be all or mostly responsible for selecting the treatment (Table 3).

Associations

There was no significant correlation between age and the belief that PCR would prolong life or help prevent a MI ($r = .10$ and $r = 0$, respectively). However, there was a significant correlation between age and the desire to participate in decision making based on the Deber scale; older patients were less likely to feel they should be the one to determine how acceptable the risks/benefits are and to determine treatment ($r = -.45$, $P = .001$ for both associations). Patients stating they should mostly determine how acceptable the risks/benefits are possessed more knowledge about the possible complications ($r = .38$, $P = .009$). Finally, there was no significant association between knowledge of complications and physician group ($r = .09$) or whether patient was scheduled for elective or possible PCR ($r = .08$).

Patient Satisfaction

Overall, patients were satisfied with the procedure. The mean (SD) patient satisfaction rating was 4.6 (0.8) on a 1-to-5 scale the morning following the procedure. Only 4 patients assigned a rating of 3 or less.

DISCUSSION

The results of this study show that many patients referred for elective PCR have expectations about the potential benefits of PCR, namely prolongation of life and prevention of future MIs that are not strongly supported by current medical literature. In addition, most patients possess little knowledge about the risks just prior to receiving PCR. Percutaneous coronary revascularization is a valuable approach to improve symptoms for patients with angina and high-grade stenosis. The ACME study of PCR for single-vessel disease found that PCR patients had more complete relief of angina, better exercise tolerance, and higher quality of life scores in comparison to medically treated patients.^{13,14} However, 43% of the patients in this study did not mention symptoms as a reason why they decided to have PCR, and when asked directly about improvement of symptoms, a substantial proportion of

patients reported they either did not have any symptoms or were uncertain about symptomatic improvement.

Relief of symptoms may not have been cited as the main reason to undergo PCR because over 70% of patients believed PCR would prolong life and/or prevent future MIs. Furthermore, many patients were referred for the procedure because of abnormal tests. Given patient's fear of the potentially catastrophic consequences of coronary artery disease, patients may have a strong investment in believing PCR can provide these 2 benefits, regardless of their current symptoms. Despite the lack of clear evidence, the possibility still exists that PCR might reduce the risk of MI and prolong life in some patient subgroups. A recent observational study suggested angioplasty did confer a survival advantage over medical treatment for patients with less severe single-vessel coronary disease, but the study was vulnerable to residual confounding from possible selection bias and its retrospective design.¹⁵

We suspect that a proportion of patients did receive an explanation of the risks and benefits because many patients had previously undergone catheterization prior to PCR and therefore received informed consent. However, our results suggest that patients apparently did not assimilate this information or the physician did not provide the risk information in an accessible format.¹⁶ Furthermore, a substantial proportion of patients specifically stated they had not had any discussion of the risks prior to the day of the procedure itself or obtained risk information from other sources, including the internet or family.

Despite their lack of understanding of the potential risks, the results of the Deber questionnaire (Table 3) show that our patients did want involvement in the decision regarding acceptability of the risks and benefits. This observation is consistent with previous studies showing that most patients do want their physicians to discuss risk with them.¹⁷ Consistent with the original Deber study, our group also deferred "problem-solving tasks" to the physician, namely the determination and likelihood of the potential benefits and risks.¹² Unlike the previous study, however, our patients accorded the physician a greater role in the decision-making process, specifically regarding choice of a treatment option. Patients may be choosing to avoid regret if the procedure is unsuccessful.

How can we help patients to make truly informed decisions in their best interest? One advocated approach is shared decision-making programs that use interactive videodisks to help patients with medical decisions.¹⁸⁻²⁰ A study investigating the effect of a shared decision-making program for patients with ischemic heart disease found that the single most important consideration among patients was whether a given treatment would increase life expectancy.²⁰ Patients also had high expectations for their chosen treatment regarding prolongation of life and prevention of future MIs. This cohort differed substantially from the present study in that 54% of patients had either acute MI or unstable angina, and 30% of their cohort was

diagnosed with 3-vessel disease.²⁰ Thus, the high expectations could have been justified, based on available evidence, for a number of these patients.⁷ Despite high patient satisfaction with the shared decision-making program, 77% of patients in this study still listed the physician as the most helpful source of information.²⁰

Patient preferences, especially when the evidence regarding treatment is a "toss-up" based on clinical grounds, should guide therapeutic decisions.^{21,22} Because individual patients place different degrees of "dysutility" for any given severity level of angina, the threshold for agreeing to undergo PCR will also vary among patients.²³ However, patient concerns about unwanted, dreaded future consequences appear to be a major component of overall patient preference. Coronary artery disease is associated with substantial dread²⁴ among patients; thus, patients may be willing to bear greater risks if they believe PCR prevents the dreaded outcomes of death or acute MI.

The problem lies with evidence that suggests PCR may produce the very outcomes the patient believes he or she is preventing. The goal should be to help patients use "informed" preferences whenever possible. What constitutes an adequate amount of information will depend on the wishes of individual patients, but we do know that patients want information, especially from their physician, about the benefits and risks involved with their care.^{12,17,23}

This study has several limitations. First, we did not ask physicians directly what they believed the indications were for their patients' PCR, and we cannot be certain about what discussions may have occurred before the procedure. Some physicians may believe that PCR can prevent MI and reduce mortality despite the current lack of clear scientific evidence. We did not review the results of exercise stress testing, functional studies, or perfusion imaging studies for this group of patients. It is possible that the physicians viewed these patients as "high risk" and thus might benefit from PCR from a prognostic standpoint.

Second, the number of patients was relatively small and drawn from only a single institution, which may affect the generalizability of the results. However, for a detailed qualitative study, the sample size is appropriate and more importantly, the results were remarkably consistent for this cohort. Third, the high educational level of the cohort also limits the generalizability of our findings. With regards to the education, however, the bias should be in the direction of greater knowledge about risks and benefits, yet this was not observed in this cohort.

Fourth, this cohort represented only a fraction of the PCR procedures done during the study period. The majority of PCRs were performed on patients with acute coronary syndromes. In addition, coronary revascularization is a rapidly evolving field and results from randomized, controlled trials often lag many years behind technical innovations such as stents and other adjunctive therapies. Finally, many patients had not had the "official" informed

consent signed at the time of the interview, but given the procedure was scheduled for the next day, patients had given an implied consent.

CONCLUSIONS

In conclusion, patients often cite factors other than symptoms as major reasons to undergo PCR, and many patients may have expectations about the long-term benefits of elective PCR that are not supported by the medical literature. Furthermore, the majority of patients were not aware of the potential risks, although they expressed a strong interest in participating in the decision to have PCR. More work is needed to define the optimal strategy to educate CAD patients, confront patient fears and unrealistic expectations about PCR, and whether specific interventions addressing these issues will change patient preferences in treatment decisions.

Dr. Holmboe and Dr. Fiellin were Robert Wood Johnson Clinical Scholars during completion of this work. Dr. Harlan M. Krumholz is a Paul Beeson Faculty Scholar. Dr. Fiellin is supported in part by grant K12DA00167 from the National Institute on Drug Abuse.

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APPENDIX 1

Core Telephone Survey Questions

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1. "Why are you having this (possible)* angioplasty?"
 2. "Do you think the angioplasty will improve your symptoms?"
 3. "Do you think the angioplasty will help you live longer?"
 4. "Do you think the angioplasty will prevent a heart attack?"
 5. "What did the doctor tell you about the possible complications or problems from having an angioplasty?"
 6. "When did you learn of these possible complications?" (Only asked if the patient mentioned a particular risk of the procedure)
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**Added when the patient was scheduled as a "cardiac catheterization with possible angioplasty."*