Informed Decision Making for Percutaneous Coronary Intervention for Stable Coronary Disease

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RESULTS
Of 59 conversations conducted by 23 cardiologists, 2 (3%) included all 7 elements of informed decision making; 8 (14%) met a more limited definition of procedure, alternatives, and risks. Specific elements significantly associated with not choosing angiography and possible PCI included discussion of uncertainty (odds ratio [OR], 20.5; 95% CI, 2.3-204.9), patient’s role (OR, 5.3; 95% CI, 1.3-21.3), exploration of alternatives (OR, 9.5; 95% CI, 2.5-36.5), and exploration of patient preference (OR, 4.8; 95% CI, 1.2-19.4). Neither the presence of angina nor severity of symptoms was associated with choosing angiography and possible PCI. In a multivariable analysis using the total number of elements as a predictor, better informed patients were less likely to choose angiography and possible PCI (OR per additional element, 3.2; 95% CI, 1.4-7.1; P = .005).

CONCLUSIONS AND RELEVANCE
In conversations between cardiologists and patients with stable angina, informed decision making is often incomplete. More complete discussions are associated with patients choosing not to undergo angiography and possible PCI.

Approximately 10 million Americans have chronic stable angina.1 For these patients, elective percutaneous coronary intervention (PCI) improves symptoms in the near term but has no effect on the risk of subsequent myocardial infarction or death.2 Nevertheless, surveys have consistently found that most patients believe that PCI reduces the risk of myocardial infarction and death,3-6 and cardiologists continue to perform it for patients with minimal or no symptoms.3 Despite evidence to the contrary, only a few cardiologists believe that PCI confers benefits beyond reduction in angina symptoms.5 In focus groups, cardiologists admit that they perform PCI based on personal beliefs in its value, to alleviate patient anxiety, and because of medicolegal fears about not performing the procedure.7,8

Less is known about why patients believe PCI reduces mortality or what impact these beliefs have on their decision making. Patients may have fixed beliefs that are not affected by accurate information presented by cardiologists, or cardiologists may simply not explicitly discuss the benefits of therapy, allowing the patient to assume the benefit. Without a full discussion of the risks and benefits, true informed consent cannot be said to have occurred.9-11 Braddock et al11 identified 7 elements of informed decision making that are required for complex decisions, such as PCI. In audiotaped discussions more than 20 years ago, Braddock et al11 found that all 7 elements were present in only 0.5% of patient-physician discussions regarding complex decisions. Moreover, only 15% included the most basic elements of informed decision making; 8 (14%) met a more limited definition of procedure, alternatives, and risks.
decision making, although few of these decisions involved a surgical procedure.

In this study, we report on the content of discussions between cardiologists and their patients regarding the decision to proceed to angiography and possible PCI for stable coronary disease. Our objective was to quantify the extent to which the elements of informed decision making are present and to correlate the completeness of informed decision making with patients’ decisions to pursue angiography and possible PCI.

Methods

Patients and Setting
We sampled existing patient-physician encounters from the Verilogue Point-of-Practice Database; 600 physicians from diverse practices and specialties across the United States contribute to this database, which is used for health services and marketing research. Cardiologists are recruited from Verilogue’s list of board-certified active cardiologists (those who prescribe medications frequently and/or see a large number of patients). Verilogue randomly selects approximately 1000 names from panel lists for a given project and then recruits (by fax, email, or telephone blast) those physicians. Panel members receive a monthly recording quota and are reimbursed for each conversation. The physician decides which conversations to record. Eligible patients are approached by front desk staff or the physician; with patient consent, the physician records the interaction. Approximately 8 of 10 agree to participate. Physicians are not informed which elements of the conversation might be of interest to Verilogue to reduce the potential for bias (Verilogue, email and oral communication, December 11, 2013).

For this study, Verilogue searched for outpatient encounters that met the following criteria: the patient was 40 years or older, the physician was a cardiologist, and the encounter took place between August 1, 2008, and August 31, 2012, and contained mention of keywords (eg, percutaneous coronary intervention, stent, angina, angiogram, or catheterization). Verilogue screened the encounters and identified discussions that included active decision making about angiography and possible PCI. Research team members with expertise in internal medicine reviewed these encounters to confirm that they contained active decision making about angiography and possible PCI. Patients who were experiencing an acute coronary syndrome and those undergoing angiography for assessment of valvular heart disease were excluded.

Data Elements
Each transcript was reviewed by 2 study team members (S.K.S. and R.K.), who determined the presence or absence of each of the 7 elements of informed decision making, using the framework of Braddock et al. These elements included (1) discussion of the patient’s role in decision making, (2) discussion of the clinical issue or nature of the decision, (3) discussion of the alternatives, (4) discussion of the pros and cons of the alternatives, (5) discussion of the uncertainties associated with the decision, (6) assessment of the patient’s understanding, and (7) exploration of patient preference. They also extracted data about elements of consent specific to PCI for stable angina that have been suggested by others, as well as information about patient symptoms. The full list of data elements appears in the eAppendix in the Supplement. To obtain multiple perspectives, one reviewer (R.K.) was a social worker with a master’s degree in public health and the other a cardiologist (S.K.S.). Both were trained by the principal investigator (M.B.R.) on 3 cases and then each coded all remaining cases independently. Discordant answers were resolved through discussion while reviewing the transcript, and the line numbers of supporting statements were recorded. Table 1 gives examples of excerpts that contain the elements. In general, we gave credit for elements even if only a minimal amount of the element was present. Thus, if a physician asked, “Do you have any questions?” we accepted that as assessment of patient understanding, even if the patient did not say anything to demonstrate understanding.

Last, we reviewed data provided by the physicians to Verilogue, including physician sex, years in practice, specialty, practice type, and geographic location. We also recorded patient demographics and medications. Optimal medical therapy was defined as aspirin, a β-blocker, and a statin.

The Baystate Medical Center Institutional Review Board determined that this study did not require approval and did not constitute human subjects research because it involved only deidentified data.

Statistical Analysis
Reviewer concordance was assessed by the κ statistic. All analyses were based on the final assessment on which the 2 reviewers (S.K.S. and R.K.) agreed. Appropriate descriptive statistics were used to summarize the data. Patients who chose angiography and possible PCI and those who did not were compared using the χ² test for categorical variables and the t test for age. The association between duration of the conversation and number of elements of informed decision making was assessed using linear regression. Univariate logistic regression models were used to relate each element to the outcome of choosing angiography and possible PCI. Because of the limited number of outcomes, it was not possible to perform traditional multivariable model building. Instead, multivariate logistic models were used to relate the number of elements to the decision to undergo angiography and possible PCI, controlling for the presence of symptoms and symptoms that limited activity, which were chosen a priori as important factors in the decision to pursue angiography. Statistical significance was established at P < .05. All analyses were conducted using SAS statistical software, version 9.3 (SAS Institute Inc) and R (cran.r-project.org).

Results

Study Population
Verilogue supplied approximately 90 transcripts, of which 59 contained discussions with cardiologists about angiography for stable coronary disease or suspected coronary dis-
Discussions lasted for a median of 11.8 minutes (range, 2.1-44.7 minutes) with a median of 2 patients (range, 1-6). Conversations were conducted by 23 cardiologists who had an extensive evaluation of the carotids, renal arteries, or heart valves.

Table 1. Transcript Excerpts of Elements of Informed Consent

<table>
<thead>
<tr>
<th>Element</th>
<th>Example</th>
<th>Additional Examples</th>
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<tr>
<td>Discussion of the patient's role in the decision making</td>
<td>1. Patient: “I don’t have a choice. I want to keep singing.” Physician: “Well, you, no, you always have a choice. But, uh, the question is, uh, we can give you medications and see if the medications help. But, uh, that’s a better fix. Because if you have many blockages, we have to see how many blockages you have. And, in general, if you open up the blockages, people have less angina than with medications alone. But the long term, the death rate and everything else is the same. People have this misconception if they get a stent, they’re going to live longer. That’s not true. The main thing stents do is they prevent symptoms. So if someone’s younger and having angina all the time, the stents will generally be better than taking medications. But the first thing is to find out the roadmap, how many blockages you got, how bad are they? You know, we don’t know that yet. The stress test is just a general idea. Things are wrong.”</td>
<td>2. Discussing the reason to do a cardiac angiography before carotid endarterectomy Physician: “Yeah, we can do it as an outpatient and if everything is good, great, go have your surgery and that’s the end of it, but if you need one of those arteries fixed, I’d want to know before you go rather than you having a heart attack on the table, midway through the middle of carotid surgery, you understand what I’m saying?”</td>
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<td>Discussion of the clinical issue or nature of the decision</td>
<td>1. Physician: “All right. So, so that, that test did show some EKG abnormalities when you were on the treadmill, and the two leading causes of the EKG changes are a blockage in the blood vessel to the heart, or possibly someone who’s had high blood pressure for a long time but it just hasn’t been treated. It’s probably, you know, statistically, it’s probably more the blockage is the more likely possibility. Um, now, there’s many ways to approach it. Uh, one possible way to investigate would be with a study called an angiogram or catheterization...” [explains angiography]. “The other possibility is that a lot of times the medicines in the body can sort of heal itself. And what can it do is it can build new blood vessels to replace old ones that are getting plugged up. So even if you do have a blockage, your neighboring blood vessels can build new blood vessels for replenished flow to the area. Um, it’s possible you, you, you, this, you may have already been doing this, because, uh, the test does suggest that there’s probably a blockage, but you did stay on the treadmill for a long time and you’re not really having a lot of chest pain, pressure, chest pain. That suggests that that may have already been going on with you, that it’s already started, yeah, there’s a blockage but you’ve already started to compensate and heal itself by building the new blood vessels, which allows you to bike and hike and...”</td>
<td>2. Physician: “Option number one is to continue the medication and do nothing. Option number two, which I think is more appropriate for you is, because of multiple risk factors and the problem to go and see what you have, and if you have anything that causes a blockage in the arteries of the heart, to open it up, okay?” 3. Physician: “The other side of the coin is just to play around with your medicines and if that doesn’t work, then do the catheterization. I can either do either way, but I’m a little concerned that he’s getting more short breath. You hadn’t expressed that before.” Physician: “I can adjust your medicine and then if you’re feeling better, good. If you’re not feeling better, then we can do the catheterization.” Patient: “Then, okay, yeah.” Physician: “Either way is acceptable to me.” Patient: “Yeah, let’s do it that way.”</td>
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<td>Discussion of the alternatives</td>
<td>1. Physician: “And if we can do the stent and not do anything more than that, it’s a very low-risk procedure. There is a high likelihood of some success here to help this problem. Now it’s not going to make your heart a normal heart. Believe that again you’ve got a weak heart muscle. Nor is it going to cure all the symptoms you had. But it may make it easier for you to breathe and prevent chest pain, and it might prevent a heart attack and more problems down the line. So those are the reasons to consider it. So I think the benefits outweigh the risks in this view. Again, if you want to think about it, you don’t have to decide today.”</td>
<td>2. Physician: “Well, they do that first and then if there are blockages, we may be able to fix the blockages in the same session. So hopefully, we’ll be able to. If we find something, hopefully, we can just perform an angioplasty instead of doing surgery. That’ll be better because it’s less invasive for you.” 3. Physician: “And it’s to find out and diagnose exactly what the problem. Certainly, it’s invasive as compared to a stress test, which is not invasive, and every time that we do a procedure, there is a certain element of risk associated with it. But, it’s a, on the balance, it’s an extremely safe test, and it gives us such important information that the benefit of doing the test far outweighs any risk.”</td>
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Quality of Informed Decision Making

Initial agreement between the 2 reviewers regarding the 7 elements of informed decision making was moderate (74% agreement, κ = 0.34). All discrepancies were reviewed, and consensus was reached on all elements (of 413 elements, 71 were upgraded and 36 were downgraded). The presence of the elements of informed decision making is given in Table 3. Examples of complete and incomplete conversations appear in the eAppendix in the Supplement. Of all the discussions, 2 (3%) included all 7 elements; 8 (14%) met a more limited definition of procedure, alternatives, and risks. More complete conversations were significantly longer than incomplete ones—an additional 1.8 (95% CI, 0.5–3.2) minutes per element. Discussion of the clinical issue was present in 57 cases (97%), whereas discussion of the patient’s role was present in 31 (53%), and discussion of alternatives was present in 15 cases (25%). Other elements that have been proposed for informed consent9 were rarely present. Specifically, use of the teach-back method occurred in 1 conversation (2%); discussion of type of stents (drug-eluting vs bare metal) occurred in 7 conversations (12%); 9 (15%) included information about the operator’s experience, although not always specific numbers of procedures performed; and 5 (8%) discussed whether insurance would cover the procedure. None mentioned cost or cost to the patient. In 41 conversations (71%), the cardiologist made it clear that if PCI were necessary, it would be performed at the same time as the angiography (ie, ad hoc).

Few differences were found between the 6 self-identified interventional cardiologists and the other cardiologists. Interventional cardiologists were more likely to discuss the pros and cons of angiography and possible PCI (83% vs 38%, P = .03). They more often discussed the patient’s role in the decision (83% vs 49%, P = .11) and fulfilled the limited definition of pro-

Table 1. Transcript Excerpts of Elements of Informed Consent (continued)

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<th>Element</th>
<th>Example</th>
<th>Additional Examples</th>
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<tr>
<td>Discussion of the uncertainties associated with the decision</td>
<td>1. Physician: “The reason we don’t just do a cath on everybody is because there’s needles and dye involved, and it’s a little bit higher risk than a stress test, which you did and there was no problems. The likelihood of having a problem with a stress test is 1 in 10 000...The likelihood of a problem with a cath is 1 in 10 000.”</td>
<td>2. Physician: “I have a mild, mild preference for that, but it has a little risk. People have had deaths, 1 in 10 000.” 3. Physician: “The question is what can be done about this other than medication, which is what we’re kind of maxing out by adding Ranexa [ranolazine]. And if we do an angiogram to look at those vessels and if we see that there is, you know, either the graft itself or a major part of that circumflex artery, which is involved, we may be able to balloon and stent it and improve that blood flow without surgery. Is there risk involved in doing it? Yeah. You’re a complicated case because, first of all, you have peripheral vascular disease. You had embolic aortic aneurysm surgery. You had previous bypass surgeries. All these grafts are difficult to get into, and you have a weak heart muscle. And you’ve also had a stroke in the past with this carotid blockage. So, you are high risk for surgery certainly.”</td>
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<td>Assessment of the patient’s understanding</td>
<td>1. Physician: “And, uh, you’ve probably heard of angioplasties and stents.” Patient: “Um-hum.” Physician: “Maybe, maybe not?” Patient: “I don’t know what stent is, angioplasty that’s when they go up with the...” Physician: “They do a little...” Patient: “Roto rooter type...” Physician: Exactly, it’s a plumbing job, okay. So, we, what we do is we find the areas of narrowing and then we put a balloon, uh, through the narrowing, little tiny, tiny balloon under x-ray guidance and, um, with the help of the balloon, we insert what’s called a stent, which is a little metal coil that actually goes in and takes away the blockage and stays in the artery forever.”</td>
<td>2. Physician: “Why do you like the angiogram? They’re risky. How many have you had? Two, or one?” Patient: “No, one.” Physician: “You’ve had one, and you like the angiograms? Well, the thing about the angiograms, it’s a peace of mind, you know what you’re looking at, so that’s the thing.” 3. Physician: “And you decided to do, to go for the medicine?” Patient: “Yes, uh, uh, for, for now, yes. Once it gets worse, of course.” Physician: “Okay, if it gets worse we can always do that another time.” Patient: “Yeah.” Physician: “You wanted to hold off on that because you were feeling okay or, I just wanted to know?” Patient: “Well, um, like yesterday I felt pretty good, and the days, the days I feel good, and other days not so good, so...” Physician: “Okay.” Patient: “Uh, well the reason I want to do that is, well I figured, uh, if I can get it done with the medicine, why go through the procedure?”</td>
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<td>Exploration of patient preference</td>
<td>1. Physician: “The thing is, despite being on cholesterol medicine, things can worsen, you’re having symptoms now. The question is, should we do a stress test and, uh, we could do a chemical stress test if you don’t think you could walk on a treadmill.” Patient: “I really, I would rather do a chemical stress.”</td>
<td>2. Physician: “Preference, your call. I want to do one of the two. If you were a bit of a chicken and you say I would take a stress test and it’ll give us good...” 3. Physician: “Okay? And then, um, you need an angiogram done, obviously. Because your stress test was abnormal, you’re having pains. But you knew that coming in.” Patient: “I don’t want another surgery.” Physician: “You don’t want another angiogram?” Patient: “I don’t, I don’t, well, no, they didn’t put me under for that one.” Physician: “We can try medications.” Patient: “I don’t like being put under.”</td>
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cEDURE, alternatives, and risks (33% vs 11%, \( P = .14 \)), although neither of these findings reached statistical significance.

**Decision to Undergo Angiography and Possible PCI**

In univariate analysis, specific elements significantly associated with not choosing angiography and possible PCI included discussion of uncertainty (odds ratio [OR], 20.5; 95% CI, 2.3-204.9), patient’s role (OR, 5.3; 95% CI, 1.3-21.3), exploration of alternatives (OR, 9.5; 95% CI, 2.5-36.5), and exploration of patient preference (OR, 4.8; 95% CI, 1.2-19.4) but not assessment of patient understanding (OR, 3.0; 95% CI, 0.8-12.3) or discussion of pros and cons of the alternatives (OR, 2.6; 95% CI, 0.8-8.7). Neither the presence of angina nor severity of symptoms was associated with choosing angiography and possible PCI. The number of elements of informed decision making had strong inverse correlation with the decision to undergo angiography and possible PCI (Figure). In a multivariable analysis using the total number of elements as a predictor and adjusting for the presence of symptoms, better informed patients were less likely to choose angiography and possible PCI (OR per additional element, 3.2; 95% CI, 1.4-7.1; \( P = .005 \)).

Physicians made recommendations in 55 cases; 49 recommended angiography and possible PCI; 44 patients (90%) followed this recommendation and 5 (10%) did not. In the 6 patients for whom physicians did not recommend PCI, all followed the recommendation. In the 4 patients for whom physicians had no recommendation, all opted not to undergo angiography and possible PCI. Finally, patients were more likely to choose angiography and possible PCI when the physician stated that the patient had a blockage that could be “fixed” (82% vs 58%, \( P = .04 \)).

**Discussion**

In this review of 59 audiotaped conversations between physicians and patients concerning angiography and possible PCI for stable coronary disease, we found that all elements required for informed decision making were present in only 2 cases (3%) and that even when using a more limited definition that included only discussion of the clinical issue alternative, and pros and cons, informed decision making occurred in only 8 cases (14%). Moreover, we found that patients who made more informed decisions were less likely to choose angiography and possible PCI. Finally, we discovered that physicians recommended angiography and possible PCI in approximately 75% of the cases, and patients usually followed that recommendation. In the few cases in which the physician made no recommendation, no patients chose to have angiography and possible PCI.

Our conversations were recorded 10 years after Braddock et al. found that only a tiny fraction of consent discussions contained the elements necessary for an informed decision. Reviewing audiotaped encounters from 1993, they found that 217 complex decisions, 1 (0.5%) contained all 7 elements and 33 (15%) contained an explanation of the procedure, alternatives, and risks. Fifteen to 20 years later, we found little improvement overall but some improvement for certain individual elements. In particular, a discussion of the patient’s role in a complex decision improved from 18% in 1993 to more than 50% in our study. In contrast, discussion of the alternatives decreased slightly.

Informed consent for angiography and possible PCI has been the focus of a number of studies. As early as 1997, Kee et al. found that patients who were about to undergo angioplasty had unrealistic expectations about the mortality benefits of that procedure and generally underestimated the risks. At least 4 more studies, 3-5,7,9 the most recent published in 2012, have confirmed these findings in diverse populations. Unfortunately, there has been little progress in addressing patients’ misconceptions. One problem has been that these studies examine only patients who have already chosen to undergo angiography and possible PCI. By analyzing the content of conversations before angiography and possible PCI, our study offers additional insight into whether the problem derives from the communication of the information or the patients’ perceptions. It would appear from these transcripts that patients are generally informed about the nature of the procedure but not the risks and benefits or the alternatives. In 2010,
The process of obtaining consent for PCI presents particular problems. Because most procedures (at least 70% in our study) are performed ad hoc while the patient is sedated on the catheterization table, it is necessary to obtain consent for angiography and PCI without knowing the exact nature of the procedure or the specific risks and benefits. One way around this dilemma is to avoid elective ad hoc PCI, as others have advocated, or to limit its use to patients in whom optimal medical therapy has failed. Another problem is that the decision making and informed consent discussions occur separately and with different physicians. Decision making for angiography often takes place in the noninvasive cardiologist’s office without full information being presented. The consent discussion happens later, usually on the morning of the procedure, with the interventional cardiologist or a surrogate, at which time the patient signs a legal document. This process is more of a formality because the operators assume the decision has already been made, and patients rarely, if ever, decide to cancel the procedure at this point. This division between the cardiologist who recommends the procedure and the one who performs it may contribute to patients not making fully informed decisions.

Medical therapy has proven benefits for coronary heart disease, but few patients were offered medical therapy as an alternative. More than two-thirds of our patients had either known coronary disease or exertional symptoms with a positive stress test result, yet almost half did not receive aspirin or a statin, and less than 10% were taking more than one antiangiogenic medication. Discussion of alternatives was strongly associated with choosing not to undergo angiography and possible PCI, but only one-quarter of cases involved such discussion. This number is substantially higher than the percentage observed by Fowler et al in a study of Medicare beneficiaries who had undergone coronary artery stenting, 6% of whom reported that the physician had discussed medication as a serious option. However, among patients in our study who chose angiography and possible PCI, 13% were told about medications; if asked about it later, some of those might not have recalled the discussion or considered it presented as something they should seriously consider.

One reason that medications were not offered may have to do with the approach to ischemia. Despite strong randomized clinical trial evidence to the contrary, many cardiologists continue to believe in the need to “stamp out” ischemia. Indeed, despite the fact that the only proven benefit of PCI for patients with stable coronary disease is symptom relief, one-quarter of the patients in this study had no symptoms. More than 80% had a positive stress test result; two-thirds of patients were told that they had blockages and that the PCI would fix the blockage. This language was strongly associated with deciding to undergo angiography and possible PCI. Fix-it language is commonly used in descriptions of surgical procedures and may create unrealistic expectations for patients.

Table 3. Quality of Informed Decision Making and Its Association With Patients Choosing Angiography and Possible PCI

<table>
<thead>
<tr>
<th>Element</th>
<th>Conversations With Element Present, No. (%)</th>
<th>No. (%) Choosing Angiography and Possible PCI</th>
<th>Adjusted* OR (95% CI) of Choosing Angiography and Possible PCI if Element Present</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s role in decision making</td>
<td>31 (53)</td>
<td>25 (89)</td>
<td>19 (61)</td>
<td>.01</td>
</tr>
<tr>
<td>Clinical issue or nature of the decision</td>
<td>57 (97)</td>
<td>1 (50)</td>
<td>43 (75)</td>
<td>.42</td>
</tr>
<tr>
<td>Alternatives</td>
<td>15 (25)</td>
<td>38 (86)</td>
<td>6 (40)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Pros and cons of the alternatives</td>
<td>25 (42)</td>
<td>28 (82)</td>
<td>16 (64)</td>
<td>.11</td>
</tr>
<tr>
<td>Uncertainties</td>
<td>6 (10)</td>
<td>43 (81)</td>
<td>1 (17)</td>
<td>.001</td>
</tr>
<tr>
<td>Assessment of patient understanding</td>
<td>37 (63)</td>
<td>19 (86)</td>
<td>25 (68)</td>
<td>.11</td>
</tr>
<tr>
<td>Exploration of patient preferences</td>
<td>32 (54)</td>
<td>24 (89)</td>
<td>20 (63)</td>
<td>.02</td>
</tr>
<tr>
<td>All 7 elements</td>
<td>2 (3)</td>
<td>44 (77)</td>
<td>0</td>
<td>.01</td>
</tr>
<tr>
<td>Clinical issue, alternatives, and pros and cons</td>
<td>8 (14)</td>
<td>42 (82)</td>
<td>2 (25)</td>
<td>.001</td>
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Abbreviations: NE, not estimable; OR, odds ratio; PCI, percutaneous coronary intervention.

* Adjusted for symptoms and limiting symptoms.
Informed Decision Making for PCI

Our study has a number of limitations. First, our sample comprised only 59 patients and 23 physicians, all of whom were paid to record their visits. It is impossible to know how selection of such physicians might bias the result, and it is reasonable to ask whether this sample, although geographically diverse, is representative of contemporary practice nationwide. We have insufficient information about the physicians to answer this question, but the characteristics of the patients and the presence of the elements of decision making are strikingly similar to those described by others. In addition, the small sample did not allow us to perform a multivariable analysis of all factors associated with choosing to undergo angiography and possible PCI or to adequately assess differences between interventional and noninterventional cardiologists.

Second, the physicians and patients knew that they were being recorded, which could have affected their behavior. If so, it is likely that this represents a best-case scenario for these physicians. Our analysis was also limited to a single conversation, often with a cardiologist who would not be performing the procedure. It is possible that patients were later provided with additional information by other members of the medical team. However, from the conversations it was clear that at the end of the visit, angiography was being scheduled. Further information provided on the day of the procedure would be unlikely to change a patient’s mind, and such a process would be highly disruptive to a busy angiography suite.

Third, although we tried to be objective, the assessment of the elements of informed decision making is inherently subjective. We coded each conversation twice, and agreement between reviewers was moderate, with disagreements resolved through discussion. Inaccurate coding would tend to attenuate associations with the outcome, so the true association may be stronger.

Fourth, although we found a strong association between the elements of informed decision making and patients’ decisions, association alone does not prove causality. In some cases, patients who were hesitant to undergo angiography and possible PCI were then presented with alternatives by theirphysicians. It is not known whether other patients, if presented with complete balanced information, would make different decisions. In particular, we did not assess appropriateness. In many cases, angiography and possible PCI were likely clinically appropriate; however, just because a procedure is appropriate does not mean that the patient wants the procedure.

Conclusions

More than a decade has passed since the Institute of Medicine identified patient-centered care as 1 of 6 aims for improving the quality of health care in the United States.24 That report identified 10 rules for health care redesign, 5 of which apply to elective PCI: care is customized to patient needs and values, the patient is the source of control, knowledge is shared, decision making is evidence based, and transparency is necessary. To date, these rules have generally not been implemented. Specific methods to improve communication have been proposed, including shared decision making,25–28 decision aids,29,30 and standardized consent documents,9 but few have been tested.29 Most recently, the Joint Commission and the American Medical Association sponsored a National Summit on Overuse30 in which they identified elective PCI as 1 of 5 overused practices. In response, they recommended that physicians (1) ensure patients are aware of the benefits and risks of PCI and (2) educate the public that PCI is not appropriate in all cases. Some members of the committee also advocated for an end to ad hoc PCI (in which diagnostic angiography and PCI are performed in the same procedure) to ensure that patients are adequately informed of the appropriate indication before agreeing to PCI. Our current study provides direct evidence of how far contemporary consent procedures are from these ideals.

As long as the reimbursement system continues to encourage PCI in all cases, it seems unlikely that the process will improve. One potential remedy would be to create new quality measures around informed consent and shared decision making.32 Such measures should avoid undue burden of documentation but still ensure that patients understand the evidence regarding the proposed intervention and indicate a clear preference for the procedure. Providing more information will take time. On the basis of the conversations in this study, providing all elements of informed decision making could add 11 minutes to describing the procedure. Still, it seems reasonable to spend even twice that amount of time discussing whether to have a procedure, such as a PCI, that has important downstream implications. Furthermore, resources spent at this stage might be offset by savings generated from performing fewer PCIs. More important, measuring and rewarding informed decision making might transform physicians’ perception of informed consent from a poorly understood legal obligation32 to a cornerstone of good medical care.
REFERENCES


