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# PCI for stable angina: A missed opportunity for shared decision-making

## ABSTRACT

Percutaneous coronary intervention (PCI) continues to be frequently performed for patients with stable coronary artery disease, despite clear evidence that it provides minimal benefit over optimal medical therapy and entails small but not inconsequential risks. Many patients and doctors do not fully understand the risks and benefits of PCI, even when presented with the evidence, and this makes informed consent challenging. The best approach is shared decision-making, with doctor and patient together choosing the best treatment option after considering the evidence and the patient's preferences.

## KEY POINTS

For patients with stable angina pectoris, PCI does not prevent myocardial infarction or death.

Optimal medical therapy with aspirin and a statin can reduce the risk of myocardial infarction and should be recommended for all patients with stable angina, regardless of whether they undergo PCI.

PCI improves symptoms of angina faster than medical therapy alone, but more than half of patients will be free of angina in about 2 years with either option.

In the absence of information to the contrary, most patients and some doctors assume that PCI is life-saving and are biased towards choosing it. As a result, patients are rarely able to give true informed consent to undergo PCI.

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**M**ULTIPLE RANDOMIZED CONTROLLED trials have compared percutaneous coronary intervention (PCI) vs optimal medical therapy for patients with chronic stable angina. All have consistently shown that PCI does not reduce the risk of death or even myocardial infarction (MI) but that it may relieve angina temporarily. Nevertheless, PCI is still commonly performed for patients with stable coronary disease, often in the absence of angina, and patients mistakenly believe the procedure is life-saving. Cardiologists may not be aware of patients' misperceptions, or worse, may encourage them. In either case, if patients do not understand the benefits of the procedure, they cannot give informed consent.

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This article reviews the pathophysiology of coronary artery disease, evidence from clinical trials of the value of PCI for chronic stable angina, patient and physician perceptions of PCI, and ways to promote patient-centered, shared decision-making.

## ■ CLINICAL CASE: EXERTIONAL ANGINA

While climbing 4 flights of stairs, a 55-year-old man noticed tightness in his chest, which lasted for 5 minutes and resolved spontaneously. Several weeks later, when visiting his primary care physician, he mentioned the episode. He had had no symptoms in the interim, but the physician ordered an exercise stress test.

Six minutes into a standard Bruce protocol, the patient experienced the same chest tightness, accompanied by 1-mm ST-segment depressions in leads II, III, and aVF. He was then referred to a cardiologist, who recommended catheterization.

Catheterization demonstrated a 95% stenosis of the right coronary artery with nonsignificant stenoses of the left anterior descending and circumflex arteries. A drug-eluting stent was placed in the right coronary artery, with no residual stenosis.

Did this intervention likely prevent an MI and perhaps save the man's life?

### ■ HOW MYOCARDIAL INFARCTION HAPPENS

Understanding the pathogenesis of MI is critical to having realistic expectations of the benefits of stent placement.

Doctors often describe coronary atherosclerosis as a plumbing problem, where deposits of cholesterol and fat build up in arterial walls, clogging the pipes and eventually causing a heart attack. This analogy, which has been around since the 1950s, is easy for patients to grasp and has been popularized in the press and internalized by the public—as one patient with a 95% stenosis put it, “I was 95% dead.” In that model, angioplasty and stenting can resolve the blockage and “fix” the problem, much as a plumber can clear your pipes with a Roto-Rooter.

Despite the visual appeal of this model,<sup>1</sup> it doesn't accurately convey what we know about the pathophysiology of coronary artery disease. Instead of a gradual buildup of fatty deposits, low-density lipoprotein cholesterol particles infiltrate arterial walls and trigger an inflammatory reaction as they are engulfed by macrophages, leading to a cascade of cytokines and recruitment of more inflammatory cells.<sup>2</sup> This immune response can eventually cause the rupture of the plaque's fibrous cap, triggering thrombosis and infarction, often at a site of insignificant stenosis.

In this new model, coronary artery disease is primarily a problem of inflammation distributed throughout the vasculature, rather than a mechanical problem localized to the site of a significant stenosis.

### Significant stenosis does not equal unstable plaque

Not all plaques are equally likely to rupture. Stable plaques tend to be long-standing and calcified, with a thick fibrous cap. A stable plaque causing a 95% stenosis may cause symptoms with exertion, but it is unlikely to

cause infarction.<sup>3</sup> Conversely, rupture-prone plaques may cause little stenosis, but a large and dangerous plaque may be lurking beneath the thin fibrous cap.

Relying on angiography can be misleading. Treating all significant stenoses improves blood flow, but does not reduce the risk of infarction, because infarction most often occurs in areas where the lumen is not obstructed. A plaque causing only 30% stenosis can suddenly rupture, causing thrombosis and complete occlusion.

The current model explains why PCI is no better than optimal medical therapy (ie, risk factor modification, antiplatelet therapy with aspirin, and a statin). Diet, exercise, smoking cessation, and statins target inflammatory processes and lower low-density lipoprotein cholesterol levels, while aspirin prevents platelet aggregation, among other likely actions.

The model also explains why coronary artery bypass grafting reduces the risk of MI and death in patients with left main or 3-vessel disease. A patient with generalized coronary artery disease has multiple lesions, many of which do not cause significant stenoses. PCI corrects only a single stenosis, whereas coronary artery bypass grafting circumvents all the vulnerable plaques in a vessel.

### ■ THE LANDMARK COURAGE TRIAL

Published in 2007, the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial<sup>4</sup> randomized more than 2,000 patients to receive either optimal medical therapy plus PCI or optimal medical therapy alone. The primary outcome was a composite of death from any cause and nonfatal MI. Patients were followed for at least 3 years, and some for as long as 7 years.

There was an initial small upward spike in the primary outcome in the PCI arm due to periprocedural events. By 5 years, the outcomes of the 2 arms converged and then stayed the same for up to 15 years.<sup>5</sup> The authors concluded that PCI conferred no benefit over optimal medical therapy in the risk of death or MI.

Some doctors dismiss the study because of its stringent entry criteria—of 35,539 patients assessed, only 3,071 met the eligibility criteria.

**Coronary artery disease is not a mechanical problem but an inflammatory one**

However, the entry criteria were meant to identify patients most likely to benefit from PCI. Many patients who undergo PCI today would not have qualified for the study because they lack objective evidence of ischemia.<sup>6</sup> To enroll, patients needed a proximal stenosis of at least 70% and objective evidence of ischemia or a coronary stenosis of more than 80% and classic angina. Exclusion criteria disqualified few patients: Canadian Cardiovascular Society class IV angina (ie, angina evoked from minimal activity or at rest); a markedly positive stress test (substantial ST-segment depression or hypotension during stage I of the Bruce protocol); refractory heart failure or cardiogenic shock; an ejection fraction of less than 30%; revascularization within the past 6 months; and coronary anatomy unsuitable for PCI.

#### ■ OTHER TRIALS SUPPORT COURAGE FINDINGS

Although COURAGE was hailed as a landmark trial, it largely supported the results of previous studies. A meta-analysis of PCI vs optimal medical therapy published in 2005 found no significant differences in death, cardiac death, MI, or nonfatal MI.<sup>7</sup> MI was actually slightly more common in the PCI group due to the increased risk of MI during the periprocedural period.

Nor has the evidence from COURAGE discouraged additional studies of the same topic. Despite consistent findings that fit with our understanding of coronary disease as inflammation, we continue to conduct studies aimed at addressing significant stenosis, as if that was the problem. Thus, there have been studies of angioplasty alone, followed by studies of bare-metal stents and then drug-eluting stents.

In 2009, Trikalinos et al published a review of 61 randomized controlled trials comprising more than 25,000 patients with stable coronary disease and comparing medical therapy and angioplasty in its various forms over the previous 20 years.<sup>8</sup> In all direct and indirect comparisons of PCI and medical therapy, there were no improvements in rates of death or MI.

Even so, the studies continue. The most recent “improvement” was the addition of frac-

tional flow reserve, which served as the inclusion criterion for the Fractional Flow Reserve versus Angiography for Multivessel Evaluation 2 (FAME 2) trial.<sup>9</sup> In that study, patients with at least 1 stenosis with a fractional flow reserve less than 0.80 were randomized to PCI plus medical therapy or to medical therapy alone. The primary end point was a composite of death from any cause, MI, and urgent revascularization. Unfortunately, the study was stopped early when the primary end point was met due to a reduction in the need for urgent revascularization. There was no reduction in the rate of MI (hazard ratio 1.05, 95% confidence interval 0.51–2.19).

The reduction in urgent revascularization has also been shown consistently in past studies, but this is the weakest outcome measure because it does not equate to a reduction in the rate of MI. There is no demonstrable harm to putting off stent placement, even in functionally significant arteries, and most patients do not require a stent, even in the future.

In summary, the primary benefit of getting a stent now is a reduced likelihood of needing one later.

#### ■ PCI MAY IMPROVE ANGINA FASTER

Another important finding of the COURAGE trial was that PCI improved symptoms more than optimal medical therapy.<sup>10</sup> This is not surprising, because angina is often a direct result of a significant stenosis. What was unexpected was that even after PCI, most patients were not symptom-free. At 1 month, significantly more PCI patients were angina-free (42%) than were medical patients (33%). This translates into an absolute risk reduction of 9% or a number needed to treat of 11 to prevent 1 case of angina.

Patients in both groups improved over time, and after 3 years, the difference between the 2 groups was no longer significant: 59% in the PCI group vs 56% in the medical therapy group were angina-free.

A more recent study has raised the possibility that the improvement in angina with PCI is primarily a placebo effect. Researchers in the United Kingdom randomized patients with stable angina and at least a 70% stenosis of one vessel to either PCI or sham PCI,

**PCI is no better than optimal medical treatment for patients with chronic stable angina**

in which they threaded the catheter but did not deploy the stent.<sup>11</sup> All patients received aggressive antianginal therapy before the procedure. At 6 weeks, there was improvement in angina in both groups, but no statistically significant difference between them in either exercise time or angina. Approximately half the patients in each group improved by at least 1 grade on the Canadian Cardiovascular Society angina classification, and more than 20% improved 2 grades.

This finding is not without precedent. Ligation of the internal mammary arteries, a popular treatment for angina in the 1950s, often provided dramatic relief of symptoms, until it was proven to be no better than a sham operation.<sup>12,13</sup> More recently, a placebo-controlled trial of percutaneous laser myocardial revascularization also failed to show improvement over a sham treatment, despite promising results from a phase 1 trial.<sup>14</sup> Together, these studies emphasize the subjective nature of angina as an outcome and call into question the routine use of PCI to relieve it.

### ■ PCI ENTAILS RISK

PCI entails a small but not inconsequential risk. During the procedure, 2% of patients develop bleeding or blood vessel damage, and another 1% die or have an MI or a stroke. In the first year after stent placement, 3% of patients have a bleeding event from the antiplatelet therapy needed for the stent, and an additional 2% develop a clot in the stent that leads to MI.<sup>15</sup>

### ■ INFORMED CONSENT IS CRITICAL

As demonstrated above, for patients with stable angina, the only evidence-based benefit of PCI over optimal medical therapy is that symptoms may respond faster. At the same time, there are costs and risks associated with the procedure. Because symptoms are subjective, patients should play a key role in deciding whether PCI is appropriate for them.

The American Medical Association states that a physician providing any treatment or procedure should disclose and discuss with patients the risks and benefits. Unfortunately, a substantial body of evidence demonstrates that this is not occurring in practice.

### Patients and cardiologists have conflicting beliefs about PCI

Studies over the past 20 years demonstrate that patients with chronic stable angina consistently overestimate the benefits of PCI, with 71% to 88% believing that it will reduce their chance of death.<sup>16–19</sup> Patients also understand that PCI can relieve their symptoms, though no study seems to have assessed the perceived magnitude of this benefit.

In contrast, when cardiologists were asked about the benefits their patients could expect from PCI, only 20% said that it would reduce mortality and 25% said it would prevent MI.<sup>18</sup> These are still surprisingly high percentages, since the study was conducted after the COURAGE trial.

Nevertheless, these differences in perception show that cardiologists fail to successfully communicate the benefits of the procedure to their patients. Without complete information, patients cannot make informed decisions.

### Cardiologists' reasons for performing PCI

If PCI cannot improve hard outcomes like MI or death in stable coronary disease, why do cardiologists continue to perform it so frequently?

Soon after the COURAGE trial, Lin et al conducted focus groups with cardiologists to find out.<sup>20</sup> Some said that they doubted the clinical trial evidence, given the reduction in the cardiac mortality rate over the past 30 years. Others remarked that their overriding goal is to stamp out ischemia, and that once a lesion is found by catheterization, one must proceed with PCI. This has been termed the “oculostenotic reflex,” ie, the interventionist sees coronary artery disease and immediately places a stent.

Atreya et al found objective evidence of this practice.<sup>21</sup> In a 2016 study of 207 patients with obstructive lesions amenable to PCI, the only factors associated with medical management were those that increased the risk of the procedure: age, chronic kidney disease, distal location of the lesion, and type C lesions (the most difficult ones to treat by PCI). More important, evidence of ischemia, presence of angina, and being on optimal medical therapy or maximal antianginal therapy were not associated with PCI.

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Despite strong evidence, trials are still under way

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When surveyed, cardiologists offered reasons similar to those identified by Lin et al, including a positive stress test (70%) and significant myocardium at risk (50%).<sup>18</sup> Optimal medical therapy failure was cited less often (40%). Over 30% identified relief of chest pain for patients who were not prescribed optimal medical therapy. Another 30% said that patient anxiety contributed to their decision, but patients who reported anxiety were not more likely to get PCI than those who did not.

**True informed consent rarely occurs**

Surveys of patients and recordings of doctor visits suggest that doctors often discuss the risks of the procedure but rarely accurately describe the benefits or mention alternative treatments, including optimal medical therapy.

Fowler et al<sup>22</sup> surveyed 472 Medicare patients who had undergone PCI in the past year about their consent discussion, particularly regarding alternative options. Only 6% of patients recalled discussing medication as a serious option with their doctor.

In 2 published studies,<sup>23,24</sup> we analyzed recorded conversations between doctors and patients in which angiography and PCI were discussed.

In a qualitative assessment of how cardiologists presented the rationale for PCI to patients,<sup>23</sup> we observed that cardiologists gave an accurate presentation of the benefits in only 5% of cases. In 13% of the conversations the benefits were explicitly overstated (eg, “If you don’t do it [angiogram/PCI], what could happen? Well, you could...have a heart attack involving that area which can lead to a sudden death”). In another 35% of cases, physicians offered an implicit overstatement of the benefit by saying they could “fix” the problem (eg, “So that’s where we start thinking, Well maybe we better try to fix that [blockage]”), without specifically stating that fixing the problem would offer any benefit. Patients were left to fill in the blanks. Conversations frequently focused on the rationale for performing PCI (eg, ischemia on a stress test) and a description of the procedure, rather than on the risks and benefits.

In a quantitative study of the same data set, we assessed how often physicians addressed the 7 elements of informed decision-making as defined by Braddock et al.<sup>24</sup>

- **Explaining the patient’s role in decision-making** (ie, that the patient has a choice to make) was present in half of the conversations. Sometimes a doctor would simply say, “The next step is to perform catheterization.”
- **Discussion of clinical issues** (eg, having a blockage, stress test results) was performed in almost every case, demonstrating physicians’ comfort with that element.
- **Discussing treatment alternatives** occurred in only 1 in 4 conversations. This was more frequent than previously reported, and appeared most often when patients expressed hesitancy about proceeding to PCI.
- **Discussing pros and cons of the alternatives** was done in 42%.
- **Uncertainty about the procedure** (eg, that it might not relieve the angina) was expressed in only 10% of conversations.
- **Assessment of patient understanding** was done in 65% of cases. This included even minimal efforts (eg, “Do you have any questions?”). More advanced methods such as teach-back were never used.
- **Exploration of patient preferences** (eg, asking patients which treatment they prefer, or attempting to understand how angina affects a patient’s life) the final element, occurred in 73% of conversations.

Only 3% of the conversations contained all 7 elements. Even using a more relaxed definition of 3 critical elements (ie, discussing clinical issues, treatment alternatives, and pros and cons), only 13% of conversations included them all.

**Discussion affects decisions**

Informed decision-making is not only important because of its ethical implications. Offering patients more information was associated with their choosing not to have PCI. The probability of a patient undergoing PCI was negatively associated with 3 specific elements of informed decision-making. Patients were less likely to choose PCI if the patient’s role in decision-making was discussed (61% vs 86% chose PCI,  $P < .03$ ); if alternatives were discussed (31% vs 89% chose PCI,  $P < .01$ ); and if uncertainties were discussed (17% vs 80% chose PCI,  $P < .01$ ).

There was also a linear relationship be-

**A visible stenosis may not actually be a problem**

tween the total number of elements discussed and the probability of choosing PCI: it ranged from 100% of patients choosing PCI when just 1 element was present to 3% of patients choosing PCI when all 7 elements were present. The relationship is not entirely causal, since doctors were more likely to talk about alternatives and risks if patients hesitated and raised questions. Cautious patients received more information.

From these observational studies, we know that physicians do not generally communicate the benefits of PCI, and patients make incorrect assumptions about the benefits they can expect. We know that those who receive more information are less likely to choose PCI, but what would happen if patients were randomly assigned to receive complete information?

### An online survey

We conducted an online survey of more than 1,000 participants over age 50 who had never undergone PCI, asking them to imagine visiting a cardiologist after having a positive stress test for stable chest pain.<sup>25</sup> Three intervention groups read different scenarios couched as information provided by their cardiologist:

- The “standard care” group received no specific information about the effects of PCI on the risk of myocardial infarction
- The “specific information” group was specifically told that PCI does not reduce the risk of myocardial infarction
- The “explanatory information” group was told how medications work and why PCI does not reduce the risk of myocardial infarction.

All 3 groups received information about the risks of PCI, its role in reducing angina, and the risks and benefits of optimal medical therapy.

After reading their scenario, all participants completed an identical questionnaire, which asked if they would opt for PCI, medical therapy, or both. Overall, 55% chose PCI, ranging from 70% in the standard care group to 46% in the group given explanatory information. Rates in the specific-information and explanatory-information groups were not statistically different from each other, but both were significantly different from that in the standard-care group. Interestingly, the more

information patients were given about PCI, the more likely they were to choose optimal medical therapy.

After reading the scenario, participants were also asked if PCI would “prevent a heart attack.” Of those who received standard care, 71% endorsed that belief, which is remarkably similar to studies of real patients who have received standard care. In contrast, only 39% of those given specific information and 31% given explanatory information held that belief. Moreover, the belief that PCI prevented MI was the strongest predictor of choosing PCI (odds ratio 5.82, 95% confidence interval 4.13–8.26).<sup>25</sup>

Interestingly, 52% of the standard care group falsely remembered that the doctor had told them that PCI would prevent an MI, even though the doctor said nothing about it one way or the other. It appears that participants were projecting their own beliefs onto the encounter. This highlights the importance of providing full information to patients who are considering this procedure.

### ■ TOWARD SHARED DECISION-MAKING

Shared decision-making is a process in which physicians enter into a partnership with a patient, offer information, elicit the patient’s preferences, and then come to a decision in concert with the patient.

Although many decisions can and should involve elements of shared decision-making, the decision to proceed with PCI for stable angina is particularly well-suited to shared decision-making. This is because the benefit of PCI depends on the value a patient attaches to being free of angina sooner. Since there is no difference in the risk of MI or death, the patient must decide if the risks of the procedure and the inconvenience of taking dual antiplatelet therapy are worth the benefit of improving symptoms faster. Presumably, patients who have more severe symptoms or experienced side effects from antianginal therapy would be more likely to choose PCI.

Despite having substantial experience educating patients, most physicians are unfamiliar with the process of shared decision-making. In particular, the process of eliciting preferences is often overlooked.

**Choice for initial therapy: put in a stent now or possibly later**

To address this issue, researchers at the Mayo Clinic developed a decision aid that compares PCI plus optimal medical therapy vs optimal medical therapy alone in an easily understandable information card.<sup>15</sup> On one side, the 2 options are clearly stated, with the magnitude of symptom improvement over time graphically illustrated and the statement, “NO DIFFERENCE in heart attack or death,” prominently displayed. The back of the card discusses the risks of each option in easily understood tables.

The decision aid was compared with standard care in a randomized trial involving patients who were referred for catheterization and possible PCI.<sup>26</sup> The decision aid improved patients’ overall knowledge about PCI. In particular, 60% of those who used the decision aid knew that PCI did not prevent death or MI vs 40% of usual-care patients—results similar to those of the online experiment.

Interestingly, the decision about whether to undergo PCI did not differ significantly between the 2 groups, although there was a trend toward more patients in the decision-aid group choosing medical therapy alone (53%) vs the standard-care patients (39%).

To understand why the decision aid did not make more of a difference, the investigators performed qualitative interviews of the cardiologists in the study.<sup>27</sup> One theme was the timing of the intervention. Patients using the decision aid had already been referred for catheterization, and some felt the process should have occurred earlier. Engaging in shared decision-making with a general cardiologist before referral could help to improve the quality of patient decisions.

Cardiologists also noted the difficulty in changing their work flow to incorporate the decision aid. Although some embraced the idea of shared decision-making, others were concerned that many patients could not participate, and there was confusion about the difference between an educational tool, which

could be used by a patient alone, and a decision aid, which is meant to generate discussion between the doctor and patient. Some expressed interest in using the tool in the future.

These findings serve to emphasize that providing information alone is not enough. If the physician does not “buy in” to the idea of shared decision-making, it will not occur.

### ■ PRACTICE IMPLICATIONS

Based on the pathophysiology of coronary artery disease and the results of multiple randomized controlled trials, it is evident that PCI does not prevent heart attacks in patients with chronic stable angina. However, most patients who undergo PCI are unaware of this and therefore do not truly give informed consent. In the absence of explicit information to the contrary, most patients with stable angina assume that PCI prevents MI and thus are biased toward choosing PCI.

Even minimal amounts of explicit information can partially overcome that bias and influence decision-making. In particular, explaining why PCI does not prevent MI was the most effective means of overcoming the bias.

To this end, shared decision aids may help physicians to engage in shared decision-making. Shared decision-making is most likely to occur if physicians are trained in the concept of shared decision-making, are committed to practicing it, and can fit it into their work flow. Ideally, this would occur in the office of a general cardiologist before referral for PCI.

For those practicing in accountable-care organizations, Medicare has recently introduced the shared decision-making model for 6 preference-sensitive conditions, including stable ischemic heart disease. Participants in this program will have the opportunity to receive payments for shared decision-making services and to share in any savings that result from reduced use of resources. Use of these tools holds the promise for providing more patient-centered care at lower cost. ■

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