



Choosing Wisely® Recommendation Analysis: Prioritizing Opportunities for Reducing Inappropriate Care

PERCUTANEOUS CORONARY INTERVENTION FOR STABLE
ISCHEMIC HEART DISEASE

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PCI FOR STABLE ISCHEMIC HEART DISEASE

Evidence Justification

The Society for Cardiovascular Angiography and Interventions recommends against the use of percutaneous coronary intervention (PCI) in patients with stable ischemic heart disease (SIHD). We summarize the reasoning provided by this society to justify the inclusion of this service, including assignment of this service into one of 5 evidentiary categories of “wasteful” services arising from the evidence on benefits, risks, and costs (Gliwa and Pearson, 2014).

Society for Cardiovascular Angiography and Interventions

Avoid PCI in asymptomatic patients with stable ischemic heart disease (SIHD) without the demonstration of ischemia on adequate stress testing or with normal fractional flow reserve (FFR) testing.

Specialty Society Rationale

Stable coronary disease is characterized by chest pain following physical exertion or emotional stress. Current treatment standards recommend lifestyle interventions as well as intensive pharmacological treatment in patients with SIHD, but many patients also receive PCI to reduce ischemia and because of perceived reductions in risk for heart attack and death. PCI has evolved from balloon angioplasty and is now typically performed by inserting a stent to open narrowed or blocked arteries in patients with coronary disease in order to restore the flow of oxygen-rich blood to the heart.

PCI may be used to reduce death and nonfatal heart attacks in patients with acute coronary syndromes, but for patients with stable SIHD, recent data suggest that angioplasty or stenting offers only a modest improvement in symptom reduction and may expose patients to unnecessary harm (Boden et al., 2007). A significant body of evidence suggests that PCI does not reduce the risk of heart attack, stroke, or death compared to optimal medical therapy alone with intensive pharmacotherapy and lifestyle interventions in patients with stable coronary disease (Boden et al., 2007; Stergiopoulos and Brown, 2012; Lin et al., 2007). Specialty society guidelines produced jointly by the American College of Cardiology, American Heart Association, and Society for Cardiovascular Angiography concur with this growing body of evidence and state that PCI

should not be performed in asymptomatic patients with stable SIHD, unless non-invasive stress testing or FFR testing reveals a moderate to severe degree of ischemia (Levine et al., 2011). Pre-PCI stress testing is important for helping physicians select patients for whom the potential benefits of PCI outweigh the harms of the invasive procedure (Lin et al., 2013). Though rare, stenting poses certain risks, including stroke, arrhythmia, heart attack, bleeding, kidney damage, and serious allergic reactions (National Heart, Lung, and Blood Institute, 2010). The cost of PCI can also be significant, ranging on average from \$20,000 - \$50,000 for commercial insurers, though prices vary by region (Bakalar, 2012; healthcarebluebook.com).

Table 1. “Wasteful Care” Evidence Category

1. Insufficient evidence to evaluate comparative benefit for any indication
2. Insufficient evidence to evaluate comparative benefit for use beyond the boundaries of established indications, frequency, intensity, or dosage
3. Adequate evidence demonstrating equivalent benefit with higher risk, higher cost, or both
4. Adequate evidence demonstrating a small comparative benefit not large enough to justify the higher risk to patients, higher cost, or both
5. Adequate evidence demonstrating improved comparative benefit, lower risk, lower cost, or both when using the intervention

Source: Gliwa and Pearson, 2014

Current Use and Variation in Practice

- *Estimated Population Affected: 27,000– 191,000**
- *Excess Cost of Practice: \$212 million – \$2.8 billion**

** Estimates are for the Medicare population only*

Source: Schwartz AL, Landon BE, Elshaug AG, et al., Measuring Low-Value Care in Medicare. *JAMA Intern Med.* 2014;174(7):1067-1076.

In spite of well-established standards of care on the appropriate use of PCI, available data suggest that use of balloon angioplasty and stent placement for stable coronary disease is an area of overuse. A retrospective study of Medicare claims data from 2009 evaluating the prevalence of low-value services found that among approximately 1.4 million beneficiaries, between 1,000 and 9,500 (0.1% – 0.7%) individuals received PCI with balloon angioplasty or stent placement for stable coronary disease (Schwartz et al., 2014). The lower range is limited to patients with a past diagnosis of myocardial infarction to exclude patients with a history of noncardiac chest pain inaccurately coded as angina. When these results are applied to the entire Medicare population, it can be estimated that approximately 27,000 – 191,000 patients undergo unnecessary cardio angioplasty or stenting. A 2011 prospective study using data from the National Cardiovascular Data Registry also demonstrated significant levels of overuse, finding that among 144,737 PCIs for non-acute indications, approximately 17,000 (12%) did not meet appropriateness criteria (Chan et al., 2011).

Other research has demonstrated that patients with stable coronary disease commonly receive PCI without first undergoing a stress test to identify moderate or severe ischemia and confirm that the intervention is needed. A retrospective study of a sample of 2004 Medicare claims data found that less than half of patients (44.5%) underwent stress testing prior to receiving elective PCI (Lin et al., 2008). Rates of stress testing varied significantly by region, ranging from 22% to 70% in some areas.

The costs of non-indicated PCI can be significant. The Schwartz study found the annual Medicare spending on PCI with balloon angioplasty and stenting for patients with SIHD to be range from \$212 million - \$2.8 billion. These estimates do not include any complications or follow-up care prompted by PCI, so the potential for cost-savings from reducing overuse may be higher.

Sociology of Practice

We performed a literature review and conducted interviews with national clinical experts representing the field of interventional cardiology to understand the multi-faceted influences that drive the use of PCI/stenting for SIHD, as well as the most effective methods to reduce inappropriate use of this service. Key themes and lessons from the literature and these conversations are summarized below.

Experts noted that several factors continue to drive the use of PCI in patients with SIHD. First, fee-for-service (FFS) reimbursement incentivizes the provision of costly interventional cardiology procedures. Physicians noted that PCI increases profits and current reimbursement systems are likely a contributor to overuse, emphasizing the need for payment reform that rewards quality and holds practitioners accountable for following clinical standards.

Second, physician education plays an important role. Experts noted that there is a significant lack of knowledge among physicians of the current clinical standards. Conventional wisdom is that PCI adds a benefit to optimal medical therapy, and though guidelines and recent evidence have challenged this theory, many physicians approach medicine with inherent biases. Focus groups with interventional and non-interventional cardiologists reveal that many clinicians continue to perceive the benefit of an open artery to be significant, even if it does not reduce the rate of heart attack or death (Lin et al., 2007). The experts interviewed noted, however, that revascularization is a clinically nuanced area and that there are a range of instances where PCI may be appropriate for asymptomatic, stable patients. More training is needed to help physicians identify the exceptional circumstances when stenting or angioplasty is appropriate to avoid overtreatment in the general population. Interviewees also noted that some cardiologists are more concerned by the perceived risks of treatment without PCI than by the potential complications caused by the procedure. Experts therefore advocated for more education and physician support to drive the uptake of Choosing Wisely recommendations and guidelines since personal opinion continues to trump evidence in many cases.

Patient education and demand are another driver of overuse. Many patients continue to equate more aggressive treatment with higher quality care. Patients who are referred to a specialist for a PCI are unsatisfied if they instead receive prescriptions and recommendations for lifestyle interventions. Patients often seek angioplasty or stenting as reassurance, lacking an understanding that medical therapy can be equally or more effective. Recent data support this claim. A study of approximately 1000 patients from across 10 US academic and community

hospitals undergoing PCI for stable coronary disease revealed that the vast majority of patients interviewed believed that the procedure would prevent future heart attacks and extend life (Kureshi et al., 2014). Experts underscored the challenge of communicating to patients that they have a blockage, but that immediate treatment is not required. Performing PCI can often be more expedient than taking the time to convince patients and their families that stenting is not required. Experts advocated for talking points to help frame conversations with patients, and emphasized the importance of further education efforts to inform patients about the comparative effectiveness of existing treatment choices and to support shared-decision making.

Though overuse of PCI remains a problem, physicians interviewed agreed that progress has been made to reduce unnecessary care. Clinically non-indicated angioplasty is identifiable using existing claims codes. Following scandals involving high-volume PCI providers, some practices now require peer-review for stenting, or a requirement that every angioplasty order receives an independent second-reading in order to avoid problems with self-referral (Mahar, 2010; Senate Finance Committee, 2010). The advent of clinical standards emphasizing the need for an index of ischemia has helped make pre-PCI fractional flow reserve (FFR) and stress testing more widespread, and has helped curb stenting and angioplasty in patients without ischemia. The inclusion of PCI on the [National Cardiovascular Data Registry](#) (NCDR) means that data are collected on the appropriate use of PCI interventions and allows practice groups and other stakeholders to measure adherence to performance standards. The registry also links to a [Physician Dashboard](#) that allows members of the American College of Cardiology (ACC) to monitor individual performance and compare their performance relative to their peers, which experts noted can be especially motivating. Experts also recognized the changing environment of practice under payment reform that rewards quality of care over volume of care as an important societal development to curb overuse.

Summary Statement: Drivers of Overuse and Opportunities for Improvement

Based on our research and conversations with national experts, this section synthesizes the major factors related to overuse, as well as any opportunities for improvement or existing best practices for reducing wasteful care.

Factors Related to Overuse		
Patient Factors	Physician Factors	Payer Factors
<ul style="list-style-type: none"> • Patient association of more aggressive treatment with quality care • Overestimation of the benefits of PCI relative to medical management 	<ul style="list-style-type: none"> • High reimbursement rate for stenting and financial incentives that reward the provision of costly procedures • Lack of knowledge of current clinical standards for PCI • Clinically nuanced area with poor understanding of when PCI is clinically appropriate for asymptomatic, stable patients 	<ul style="list-style-type: none"> • Payment models that reward volume
Opportunities for Improvement/Current Best Practices		
Opportunities for Improvement	Current Best Practices	
<ul style="list-style-type: none"> • Make greater use of global payment arrangements that reduce incentives to overtreat patients • Provide training and education to increase awareness among physicians of the appropriate use of PCI and of the importance of pre-PCI stress testing or FFR • Develop talking points to help frame conversations with patients on the comparative effectiveness of existing treatment choices and to support shared-decision making 	<ul style="list-style-type: none"> • National quality registries that monitor performance and allow individual physicians to assess the rate of PCI relative to their peers. • Requirements for peer-review to avoid self-referrals for PCI procedures 	

Summary Rating

This section synthesizes the information provided previously and presents a recommended priority ranking of whether this service is likely to represent the best opportunity for policy makers to improve practice and drive change. These rankings are based on considerations of 5 factors illustrated in the table below.

<i>Criteria</i>	<i>Ranking</i>
<i>Level of overuse</i>	★ = Limited overuse ★ ★ = Moderate overuse ★ ★ ★ = Substantial overuse
<i>Magnitude of individual patient harm</i>	★ = Limited harm ★ ★ = Moderate harm ★ ★ ★ = Substantial harm
<i>Ease of overcoming patient, clinician, and system barriers to reduce inappropriate care</i>	★ = Limited ease ★ ★ = Moderate ease ★ ★ ★ = Substantial ease
<i>Potential to leverage existing change programs and policy efforts</i>	★ = Limited potential ★ ★ = Moderate potential ★ ★ ★ = Substantial potential
<i>Amount of potential savings</i>	★ = Limited savings ★ ★ = Moderate savings ★ ★ ★ = Substantial savings

<i>Category</i>	<i>Score</i>	<i>Rationale</i>
<i>Level of overuse</i>	★★★	<ul style="list-style-type: none"> Determined to be a significant level of overuse according to multiple studies comparing areas of low value care among Medicare beneficiaries
<i>Magnitude of individual patient harm</i>	★★	<ul style="list-style-type: none"> Adverse events are rare, but significant, and include the potential for heart attack or long-term bleeding
<i>Ease of overcoming patient, clinician, and system barriers to reduce inappropriate care</i>	★★	<ul style="list-style-type: none"> Financial incentives will gradually diminish or disappear as reimbursement systems become more value-based Algorithms available to identify unnecessary use with existing billing codes
<i>Opportunity to leverage existing change programs and policy efforts</i>	★★	<ul style="list-style-type: none"> Existing clinical guidelines with multiple society buy-in signifies opportunity for collaboration and dissemination of standards Existing efforts to track and monitor performance in this area in quality registries
<i>Amount of potential savings</i>	★★★	<ul style="list-style-type: none"> Tests are very expensive, and eligible patient population is significant

References

- Bakalar N. No extra benefits are seen in stents for coronary artery disease. *The New York Times*. February 27, 2012. Available at <http://www.nytimes.com/2012/02/28/health/stents-show-no-extra-benefits-for-coronary-artery-disease.html?pagewanted=all&r=2&>.
- Boden W, O'Rourke RA, Koon TK, et al. Optical medical therapy with or without PCI for stable coronary artery disease. *N Engl J Med*. 2007; 356:1503-1516.
- Chan PS, Patel MR, Klein LW, et al. Appropriateness of percutaneous coronary intervention. *JAMA*. 2011;306(1):53-61.
- Gliwa C, Pearson SD. Evidentiary rationales for the Choosing Wisely "Top 5" lists. *JAMA*. 2014;311(14):1443-1444.
- Healthcare Bluebook. Coronary Angioplasty. Available at <https://healthcarebluebook.com/page/ProcedureDetails.aspx?id=281&dataset=MD&g=Coronary+Angioplasty>. Accessed November, 2014.
- Kursehi F, Jones PG, Buchanan DM, Abdallah MS, Spertus JA. Variation in patients' perceptions of elective percutaneous coronary intervention in stable coronary artery disease: cross sectional study. *BMJ*. 2014; 349:g5309.
- Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation*. 2012;125(8):e412.
- Lin GA, Dudley RA, Lucas FL, Malenka DJ, Vittinghoff E, Redberg RF. Frequency of stress testing to document ischemia prior to elective percutaneous coronary intervention. *JAMA*. 2008;300(15):1765-73.
- Lin GA, Dudley RA, Redberg RF. Cardiologists' use of percutaneous coronary interventions for stable coronary artery disease. *Arch Intern Med*. 2007;167(15):1604-9.
- Lin GA, Lucas FL, Malenka DJ, Skinner J, Redberg RF. Mortality in Medicare patients undergoing elective percutaneous coronary intervention with or without antecedent stress testing. *Circ Cardiovasc Qual Outcomes*. 2013;6(3):309-314.
- Mahar M. Stent scandal: A shocking story, but not news. *Health Beat*. December 8, 2010. Available at <http://www.healthbeatblog.com/2010/12/stent-scandal-a-shocking-story-but-not-news/>. Accessed November, 2014.
- National Cardiovascular Data Registry. Available at <https://www.ncdr.com/webncdr/home/>. Accessed November 2014.

National Heart, Lung, and Blood Institute. What are the risks of percutaneous intervention? 2010. Available at <http://www.nhlbi.nih.gov/health/health-topics/topics/angioplasty/risks>. Accessed November, 2014.

Schwartz AL, Landon BE, Elshaug AG, et al., Measuring Low-Value Care in Medicare. *JAMA Intern Med*. 2014;174(7):1067-1076.

Senate Finance Committee. Staff report on cardiac stent usage at St. Joseph Medical Center. 2010. Available at <http://s3.documentcloud.org/documents/17685/senate-finance-committee-report-on-cardiac-stent-usage-at-st-joseph-medical-center.txt>.

Stergiopoulos K, Brown DL. Initial coronary stent implantation with medical therapy vs medical therapy along for stable coronary artery disease. *Arch Intern Med*. 2012;172(4):312-319.