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Editorial

High-Risk Percutaneous Coronary Intervention in Patients With Stable Ischemic Heart Disease

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Interventional cardiologists often face difficult decision-making concerning percutaneous coronary intervention (PCI) in high-risk patients. They will rightly feel that the procedure may be technically feasible, but at the risk of higher complications. The decision concerning whether to proceed with a procedure in such situations is best guided by appropriate, carefully analyzed data. Many high-risk PCI patients are in the midst of ST-elevation myocardial infarction or other acute coronary syndromes. While these patients are clearly at high risk, the urgency of the clinical situation demands that the procedure be done. Indeed, clinical trial data strongly support high-risk PCI in patients with acute ischemia [1,2]. Thus, while it is always appropriate to consider the individual patient, there is no overall issue concerning whether to perform PCI in the setting of acute ischemia. However, decision-making in the setting of high-risk procedures in patients who are otherwise stable may actually be more difficult. In such patients, we lack clinical trial data showing that intervention will improve outcome, and this particular group of patients overall has not been thoroughly studied [3,4]. In this regard, the paper in this issue of the journal by Iverson et al. is timely and important [5].

This is a single-center study from the Minneapolis Heart Institute. The study population comprised 1975 patients without acute coronary syndromes undergoing PCI between 6/29/09 and 12/30/2016. High-risk procedures included left main PCI, chronic total occlusion, atherectomy, multivessel PCI, bifurcation PCI, PCI in patients who had previous coronary artery bypass surgery, and patients with a left ventricular ejection fraction of ≤30% or use of hemodynamic support. There were 1230 high-risk patients and 745 non-high-risk patients. Over the course of the study, the percentage of high-risk patients varied, but with no clear trend. However, it is clear that the majority are actually at high risk. While "high risk" was defined based on anatomic and procedural details, the high-risk patients were also sicker, with more comorbidity, including prior myocardial infarction, cerebrovascular disease, peripheral vascular disease, and congestive heart failure. High-risk patients required more stents (2.0 vs. 1.0, $p<0.001$). Periprocedural complications were more common in high-risk patients (2.9% vs. 1.1%, $p=0.01$), as was in-hospital mortality (1.0% vs. 0.13%, $p=0.04$). In a multivariable model, high-risk patients had 2.92 (95% CI 1.16 to 7.36) times the risk of technical failure and 2.21 (95% CI 0.91 to 5.35) times the risk of periprocedural complications.

A number of important conclusions can be drawn from this study. Overall, the patient outcomes were highly satisfactory. In the non-high–risk population, complications and mortality were uncommon. In such patients, it should be expected that event rates would be quite low. However, the event rates were also low in the high-risk population, with a 1.0% mortality rate. Thus, in selected high-risk patients, PCI would appear to be reasonably safe. Nonetheless, there are a number of important limitations to this study. This was a single-center study from a leading institution. As such, these results may not be generalizable to other institutions. The number of events was small, making it difficult to accurately predict which patients are at high risk. Indeed, in the multivariable model, high-risk PCI showed a trend, but not a statistically significant increase in the incidence of periprocedural complications compared to non-high risk. While the patients are well-characterized, there are a number of variables that were not collected or at least not shown, such as frailty or malignancy. Also, the anatomic details are limited. Thus, there may be high-risk patients who are truly at higher risk than the average of the high-risk group, as well as patients who are not actually at high risk. In particular, the reasons patients were considered high risk varied, and the complications and mortality rates across these different subgroups may vary as well; the study population was too small to permit this to be sorted out. A larger, multi-institutional study, perhaps from the National Cardiovascular Data Registry (NCDR), would be needed to develop specific models for the relevant outcomes in this group of patients as well as the subgroups [6,7]. Nonetheless, overall, the results are reassuring.

Thus, we have learned that most of the time, PCI can be safely performed in high-risk patients with stable ischemic heart disease. However, should these patients undergo PCI? A 1.0% mortality rate is not

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negligible and, thus, for PCI to be performed, there should be the expectation that the procedure will offer the patients benefit. In this regard, we must remember that clinical trial data still do not offer convincing evidence that PCI can prevent death or myocardial infarction in any group of patients with stable ischemic heart disease. The majority of these patients had angina or atypical chest pain. The COURAGE trial has shown that PCI will, on average, relieve angina compared with medical therapy for at least several years, providing potential justification for PCI in these patients [8]. The ORBITA trial, with blinded sham controls, casts some doubt on the reduction of angina seen in COURAGE [9]. However, the high-risk patients in the study by Iverson and colleagues would not be characteristic of those in ORBITA and would appear to be sicker on average compared to those in COURAGE as well. Thus, if these high-risk patients had disabling angina or perhaps even less-than-disabling angina in certain anatomic subsets (e.g., left main disease), then PCI would be indicated and could be justified by American College of Cardiology appropriate use criteria [10]. The current study does lack follow-up, so that long-term event rates and symptomatic status cannot be assessed. This leaves us uncertain as the effect of the procedure on outcome and symptomatic status. The ISCHEMIA trial, with results expected in late 2019, may help to better define outcomes and select patients in whom PCI will offer benefit as compared with medical therapy [11].

Where the Iverson et al. study is most helpful is in helping the decision-making in the era where institutions and individual operators are being benchmarked and subjected to public reporting. This will leave operators wary of performing PCI, as they may fear that they will be judged if such patients do suffer complications. In principle, covariates should adjust for higher-risk patients. However, operators will remain distrustful that statistical approaches will adequately adjust the level of risk [12]. More studies, especially from the NCDR, may help to further assess the incidence of complications and allow for better, more robust risk prediction. New approaches to machine learning, where artificial intelligence can examine electronic health records, may also help to define risk [13]. Nonetheless, risk prediction is imperfect and is certain to remain so. In all likelihood, there will be patients at high risk in whom there is compelling reason, largely based on symptoms, for proceeding with PCI, while the incidence of complications will remain somewhat uncertain. In this setting, interventional cardiologists, in using shared decision-making with patients and family along with a heart team approach that includes cardiothoracic surgeons, will need to make the best-informed decision they can as to whether to proceed with PCI [14,15].

References

[1] Bavry AA, Kumbhani DJ, Rassi AN, Bhatt DL, Askari AT. Benefit of early invasive therapy in acute coronary syndromes: a meta-analysis of contemporary randomized clinical trials. J Am Coll Cardiol 2006;48(7):1319–25.

[2] Mehta SR, Cannon CP, Fox KA, Wallentin L, Boden WE, Spacek R, et al. Routine vs selective invasive strategies in patients with acute coronary syndromes: a collaborative meta-analysis of randomized trials. JAMA 2005;293(23):2908–17.

[3] Boden WE, O'Rourke RA, Teo KK, Hartigan PM, Maron DJ, Kostuk WJ, et al. Optimal medical therapy with or without PCI for stable coronary disease. N Engl J Med 2007;356(15):1503–16.

[4] Group BDS, Frye RL, August P, Brooks MM, Hardison RM, Kelsey SF, et al. A randomized trial of therapies for type 2 diabetes and coronary artery disease. N Engl J Med 2009;360(24):2503–15.

[5] Iverson A, Stanberry LI, Tajti P, Garberich R, Antos A, Burke MN, et al. Prevalence, trends, and outcomes of higher risk percutaneous coronary interventions among patients without acute coronary syndromes. Cardiovasc Revasc Med 2019;20(4):289–92.

[6] Peterson ED, Dai D, DeLong ER, Brennan JM, Singh M, Rao SV, et al. Contemporary mortality risk prediction for percutaneous coronary intervention: results from 588,398 procedures in the National Cardiovascular Data Registry. J Am Coll Cardiol 2010;55(18):1923–32.

[7] Weintraub WS, Grau-Sepulveda MV, Weiss JM, Delong ER, Peterson ED, O'Brien SM, et al. Prediction of long-term mortality after percutaneous coronary intervention in older adults: results from the National Cardiovascular Data Registry. Circulation 2012;125(12):1501–10.

[8] Weintraub WS, Spertus JA, Kolm P, Maron DJ, Zhang Z, Jurkovitz C, et al. Effect of PCI on quality of life in patients with stable coronary disease. N Engl J Med 2008;359(7):677–87.

[9] Al-Lamee R, Thompson D, Dehbi HM, Sen S, Tang K, Davies J, et al. Percutaneous coronary intervention in stable angina (ORBITA): a double-blind, randomised controlled trial. Lancet 2018;391(10115):31–40.

[10] Patel MR, Bailey SR, Bonow RO, Chambers CE, Chan PS, Dehmer GJ, et al. ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 appropriate use criteria for diagnostic catheterization: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society of Critical Care Medicine, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. J Am Coll Cardiol 2012;59(22):1995–2027.

[11] Group ITR, Maron DJ, Hochman JS, O'Brien SM, Reynolds HR, Boden WE, et al. International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) trial: Rationale and design. Am Heart J 2018;201:124–35.

[12] Weintraub WS, Garratt KN. Challenges in Risk Adjustment for Hospital and Provider Outcomes Assessment. Circulation 2017;135(4):317–9.

[13] Johnson KW, Torres Soto J, Glicksberg BS, Shameer K, Miotto R, Ali M, et al. Artificial Intelligence in Cardiology. J Am Coll Cardiol 2018;71(23):2668–79.

[14] Barry MJ, Edgman-Levitan S. Shared decision making–pinnacle of patient-centered care. N Engl J Med 2012;366(9):780–1.

[15] Holmes Jr DR, Rich JB, Zoghbi WA, Mack MJ. The heart team of cardiovascular care. J Am Coll Cardiol 2013;61(9):903–7.