

Temporal Trends and Site Variation in High-Risk Coronary Intervention and the Use of Mechanical Circulatory Support: Insights From the Veterans Affairs Clinical Assessment Reporting and Tracking (CART) Program

Rory S. Bricker, MD; Thomas J. Glorioso, MS; Omar Jawaid, MD; Mary E. Plomondon, PhD; Javier A. Valle, MD, MSc; Ehrin J. Armstrong, MD, MSc; Stephen W. Waldo, MD

Background—Patients undergoing percutaneous coronary intervention (PCI) are older with greater medical comorbidities and anatomical complexity than ever before, resulting in an increased frequency of nonemergent high-risk PCI (HR-PCI). We thus sought to evaluate the temporal trends in performance of HR-PCI and utilization of mechanical circulatory support in the largest integrated healthcare system in the United States.

Methods and Results—A cohort of high-risk adult patients that underwent nonemergent PCI in the Veterans Affairs Healthcare System between January 2008 and June 2018 were identified by objective clinical, hemodynamic, and anatomic criteria. Temporal trends in the performance of HR-PCI, utilization of mechanical circulatory support, and site-level variation were assessed. Of 111 548 patients assessed during the study period, 554 met 3 high-risk criteria whereas 4414 met at least 2 criteria for HR-PCI. There was a significant linear increase in the proportion of interventions that met 3 (P<0.001) or at least 2 (P<0.001) high-risk criteria over time, with rates approaching 1.9% and 11.2% in the last full calendar year analyzed. A minority of patients who met all high-risk criteria received PCI with mechanical support (15.7%) without a significant increase over time (P=0.193). However, there was significant site-level variation in the probability of performing HR-PCI (4.0-fold higher likelihood) and utilizing mechanical circulatory support (1.9-fold higher likelihood) between high and low utilization sites.

Conclusions—The proportion of cases categorized as HR-PCI has increased over time, with significant site-level variation in performance. The majority of HR-PCI cases did not utilize mechanical support, highlighting a discrepancy between current recommendations and clinical practice in an integrated healthcare system. (*J Am Heart Assoc.* 2019;8:e014906. DOI: 10.1161/JAHA.119.014906.)

Key Words: health outcomes • mechanical circulatory support • percutaneous coronary intervention

 \mathbf{P} ercutaneous coronary intervention (PCI) has evolved over the past 2 decades, given that the patient population receiving this therapy has become older with significantly

Correspondence to: Stephen W. Waldo, MD, Rocky Mountain Regional VA Medical Center, 1700 N Wheeling St, Aurora, CO 80045. E-mail: stephen.waldo@va.gov

Received October 15, 2019; accepted October 30, 2019.

greater medical comorbidities.¹ The anatomical complexity of individuals undergoing PCI has also increased given that more medically acute patients may be deemed ineligible for surgical revascularization,^{2,3} whereas advances in procedural techniques and devices allow them to undergo treatment in the cardiac catheterization laboratory. This has resulted in the growth of nonemergent high-risk intervention, variably defined as percutaneous revascularization of vessels supplying a large myocardial territory in the setting of severely depressed left ventricular systolic function.^{4–6} A number of studies have demonstrated that high-risk PCI (HR-PCI) performed in these patients may be associated with significant morbidity and mortality.^{7,8} Because of this, numerous adjunct supportive therapies have been developed to reduce the risk of this procedure.

Mechanical circulatory support may decrease adverse outcomes during HR-PCI. Initial studies evaluating intra-aortic

From the University of Colorado School of Medicine, Aurora, CO (R.S.B., O.J., J.A.V., E.J.A., S.W.W.); Department of Medicine, VA Eastern Colorado Health Care System, Denver, CO (T.J.G., M.E.P., J.A.V., E.J.A., S.W.W.).

Accompanying Tables S1, Figures S1 and S2 are available at https://www. ahajournals.org/doi/suppl/10.1161/JAHA.119.014906

^{© 2019} The Authors. Published on behalf of the American Heart Association, Inc., by Wiley. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

Clinical Perspective

What Is New?

- A novel objective definition for high-risk coronary intervention of native vessels has been developed and validated.
- Temporal trends in high-risk intervention suggest a significant increase over time, with significant variation across sites.
- Mechanical support utilization occurred in a minority of high-risk cases with similar site variation.

What Are the Clinical Implications?

- A novel objective definition for high-risk coronary intervention of native vessels can be applied to additional patients prospectively.
- Significant site variation in the performance of high-risk intervention and utilization of mechanical support suggests an opportunity to create clearly defined practice pathways to homogenize care and improve clinical outcomes.

balloon pump counterpulsation in this setting have not demonstrated a significant reduction in major adverse cardiovascular events or periprocedural mortality.9,10 Novel mechanical support technologies that provide greater degrees of circulatory assistance have since been developed, with the hopes of improved clinical outcomes. A percutaneously inserted axial flow pump (Impella) has been demonstrated to improve hemodynamic parameters among patients undergoing highrisk intervention, with several multicenter registries demonstrating the safety and feasibility of using this device.^{11,12} One randomized trial has also documented the potential efficacy of an axial flow pump, with a trend toward a reduction in major adverse events 90 days postprocedure that did not reach statistical significance.¹³ Other percutaneous ventricular support devices (eg, Tandem Heart) have also been investigated, demonstrating similar findings.^{14,15} These novel percutaneous mechanical support therapies may provide additional protection for HR-PCI, leading to their recommendation by expert committees.^{15–17} However, the temporal trends in the performance of HR-PCI and utilization of mechanical support are unknown.

With this in mind, the present project sought to evaluate the temporal trends and site-level variability in the performance of high-risk coronary intervention and the use of concomitant mechanical support in the largest integrated healthcare system in the United States, the Veterans Affairs (VA) Healthcare System.

Methods

The data that support the findings of this study are available from the corresponding author on reasonable request, though

Population

The VA Clinical Assessment Reporting and Tracking Program is a national quality and safety program for invasive cardiac procedures within the VA Health Care System. As described previously, this mandatory program captures and compiles standardized patient and procedural data elements for all invasive cardiac procedures performed in VA cardiac catheterization laboratories.¹⁸ The data elements surveyed are derived from previously established data definitions from the NCDR (National Cardiovascular Data Registry), and the data set is independently assessed for accuracy and validity on a routine basis.^{19,20} The present study focused on adult (>18 years) patients that underwent nonemergent HR-PCI between January 2008 and June 2018. HR-PCI was defined according to previously published studies and consensus documents.4-6 More specifically, a PCI was deemed high risk if the patient undergoing the procedure met 3 specific criteria:

- Clinical criteria: medical comorbidities resulting in an estimated clinical risk of periprocedural mortality to be >1.1% by the NCDR for Catheterization Percutaneous Coronary Intervention (CathPCI) Mortality model.²¹
- Hemodynamic criteria: evidence of hemodynamic impairment, characterized as a left ventricular ejection fraction ≤35%. This value was derived from previously published clinical consensus documents on the definition of highrisk percutaneous coronary intervention.^{4–6}
- Anatomical criteria: evidence of anatomical coronary complexity, as defined using the simplified anatomical risk score for coronary arteries (VA SYNTAX).²² High-risk anatomical complexity was defined as a VA SYNTAX score >15 (the highest tertile of anatomical complexity).

The primary cohort included patients that met all 3 of these criteria, ensuring that this was very specific for a highrisk subpopulation of patients undergoing coronary intervention. A subsequent analysis was performed for patients that met at least 2 of these 3 criteria. All procedures were reviewed and approved by the Colorado Multiple Institutions Review Board, with a waiver of informed consent.

Measurements

Patient and procedural characteristics were derived from the linked electronic medical record and cardiac catheterization report documentation. The procedural details of the coronary intervention, including the utilization of mechanical support such as an intra-aortic balloon pump or ventricular assist device (Impella/Tandem Heart), was documented by the

operators at the time of the procedure. A chart review was performed to confirm the use and type of mechanical support used in all cases where it was documented by the operators. Clinical outcomes were ascertained through a review of administrative billing codes for readmission for recurrent myocardial infarction or readmission for stroke (Table S1). Mortality was ascertained from the VA Information Resource Center Vital Status File, which includes vital data from the Beneficiary Identification Record Locator Subsystem Death File, VA Medicare Vital Status File, and the Social Security Administration Death Master File.²³

Outcomes

Temporal trends for high-risk coronary intervention and utilization of mechanical support among those undergoing high-risk intervention were tabulated as a function of time. Clinical outcomes included major adverse cardiovascular and cerebrovascular event events, defined as death, readmission for myocardial infarction, readmission for stroke, or repeat revascularization.

Statistical Analysis

A comparison among all patients undergoing PCI with those that met 3 or at least 2 high-risk criteria were done in a standard fashion, with separate testing performed with groups not identified as high risk using *t* tests for continuous variables and chi-squared tests for categorical variables. To assess temporal trends in performance of high-risk coronary intervention, volumes were tabulated for each quarter and plotted. Linear models using natural cubic B-spline for time were run and spline results were plotted to further explore these trends using the "splines" package in R (R Core Team, 2017). Because the trends appeared linear, we evaluated the linear association by removing the spline terms and adding a continuous predictor for quarter to the model. When assessing rates of high-risk coronary intervention and utilization of mechanical support, log-binomial models were used in place of linear models with similar use of natural cubic B-splines and a continuous predictor for time to assess linear trend on the log scale. These models did not adjust for potential confounders nor did they account for clustering of results by site, given the small sample sizes. Site-level variation in high-risk intervention and mechanical support was then assessed by adding a random intercept to the log-binomial models that contained the spline terms for time trend. Following a reference-effect measure methodology, we summarized site variation from the model by presenting the relative "risk" of high-risk intervention or use of mechanical support for a patient at a site more likely to perform this procedure (90th percentile of random-effects distribution) compared with a similar patient at a low "risk" site (10th percentile).²⁴ Finally, the temporal trend in major adverse events (death, readmission for myocardial infarction, readmission for stroke, or repeat revascularization) was assessed with a Cox proportional hazards model. Adjustment covariates within the model included demographic characteristics (age, race, and body mass index), medical comorbidities (congestive heart failure, chronic kidney disease, chronic obstructive pulmonary disease, cerebrovascular disease, diabetes mellitus, depression, glomerular filtration rate, hypertension, hyperlipidemia, peripheral artery disease, previous myocardial infarction, and previous coronary intervention), procedural details (elective procedure, indication, and vessel treated) as well as a frailty term to account for clustering of results by facility. Natural cubic B-splines for calendar time were included to examine the temporal trends, and the results are presented for the relative hazard of major adverse events following high-risk intervention performed at a specific time in the study period relative to an intervention occurring at the start of the study (2008), with all events censored at 2 years. A continuous predictor for time was again added to assess linear trend on the loghazard scale. All analyses were performed with R (R Core Team, 2017). A 2-tailed P<0.05 was considered statistically significant.

Results

Population

Over the study period, 111 548 PCIs were performed in the VA Healthcare System. Patients were excluded from the cohort if they were considered an emergent case with concomitant cardiogenic shock (1443) or ST-segment-elevation myocardial infarction (7217). Additional subjects were excluded if they had a previous coronary artery bypass (33 166), given that anatomical complexity could not be accurately calculated, or if they were undergoing a staged intervention after an index procedure (4883). Finally, patients with missing clinical (3954), hemodynamic (9219), or anatomical (28 950) information were excluded because it made it impossible to determine whether an intervention for these patients would be considered high risk. The majority of those excluded with missing anatomical information did not have coronary dominance denoted by the operators performing the procedure, making calculation of a simplified anatomical complexity score impossible. This resulted in an analytical cohort of 46 022 patients, of which 554 (1.2%) met 3 criteria and 4414 (9.5%) met at least 2 criteria for an HR-PCI (Figure 1). The number of patients from this cohort that met the medical, hemodynamic, or anatomical criteria for an HR-PCI are depicted in Figure 2.



Figure 1. Patients included in the analytical cohort.

Patient Characteristics

Demographic and clinical characteristics of patients undergoing PCI are shown in Table 1, stratified by the number of high-risk criteria that a given patient fulfilled. Patients that met either 3 or at least 2 high-risk criteria were significantly older and more likely to have medical comorbidities when compared with those not considered HR-PCI, including increasing burden of congestive heart failure (P<0.001), chronic kidney disease (P<0.001), chronic obstructive pulmonary disease (P<0.001), diabetes mellitus (P<0.001), and peripheral artery disease (P<0.001). The proportion of patients undergoing intervention that had previous myocardial infarctions (P<0.001) or strokes (P<0.001) was also significantly higher among those that met 2 or 3 high-risk criteria.

The procedural characteristics of patients undergoing PCI are shown in Table 2, stratified by the number of high-risk criteria that a given patient fulfilled. Patients that met either 3 or 2 high-risk criteria had a higher proportion of non–ST-segment–elevation myocardial infarctions (P<0.001) compared with those undergoing interventions that did not meet any high-risk criteria. The raw proportion of mechanical support used was higher among patients meeting at least 3 (P<0.001) or 2 (P<0.001) high-risk criteria. The type of

mechanical support used in each case is depicted in Figure S1, with intra-aortic balloon pumps used in 63% (3 criteria) or 58% (2 criteria) of cases and axial flow pumps used in 36% (3 criteria) or 42% (2 criteria) of cases.

Temporal Trends

Temporal trends in HR-PCI are summarized in Figure 3. As demonstrated, the number of patients undergoing PCI that met 3 (P<0.001) or at least 2 (P<0.001) high-risk criteria had a significant linear increase during the time period under investigation. Similarly, we observed a significant linear increase on the log scale in the proportion of interventions that met 3 (P<0.001) or at least 2 (P<0.001) high-risk criteria among all interventions, with rates approaching 1.9% and 11.2% of the total case volume in the entire healthcare system in the last full calendar year analyzed, respectively. Temporal trends in mechanical support utilization among those undergoing high-risk coronary intervention are summarized in Figure 4. The proportion of patients receiving mechanical support had significant linear increase on the log scale among patients that met at least 2 high-risk criteria (P=0.026); however, the observed increase was not significant among those meeting 3 high-risk criteria (P=0.193). Temporal trends



Figure 2. Number of patients that met each *high-risk* criteria. After exclusions, 41 608 patients did not meet any of the *high-risk* criteria. NCDR CathPCI indicates National Cardiovascular Data Registry for Catheterization Percutaneous Coronary Intervention.

in the type of mechanical support utilization are reproduced in Figure 2, demonstrating a linear increase in utilization of mechanical support other than a balloon pump among patients meeting 3 (P=0.001) and at least 2 (P≤0.001) criteria for a high-risk intervention. There were no cases of extracorporeal membrane oxygenation supported intervention in the cohort.

Temporal trends in major adverse cardiovascular and cerebrovascular events for those meeting 3 or 2 high-risk criteria, with median follow-up of 10.7 and 19.4 months, respectively, are shown in Figure 5. In both cases, there was no discernable trend for adverse outcomes over time with nonsignificant linear trend on the log-hazard scale (P=0.179).

Site Variation

In the evaluation of site variation, a patient was 4.0 times more likely to receive a high-risk coronary intervention and 1.9 times more likely to receive mechanical support during a high-risk coronary intervention at a high utilization site (90th percentile) compared with being treated at a low utilization site (10th percentile) when requiring 3 high-risk criteria be met. Similarly, there was a 2.6 times higher likelihood for high-risk coronary intervention and a 2.1 times higher likelihood for mechanical support during a high-risk coronary intervention at a high-performing site compared with the lowperforming site when requiring that patients meet at least 2 high-risk criteria.

Discussion

The present analysis evaluated the temporal trends in highrisk coronary intervention and utilization of mechanical support in the largest integrated healthcare system in the United States. As the data demonstrate, the proportion of coronary interventions classified as high risk has steadily increased with time. Mechanical support utilization has also increased, although to a lesser degree and with significant site-level variation. These data provide important insights into the contemporary practice of high-risk percutaneous intervention as well as potential opportunities to improve care for this vulnerable population.

Evaluation of the temporal trends of HR-PCI requires a standardized definition. As acknowledged in previous consensus statements, "At present, no single, unifying definition for HR-PCI exists."⁴ However, 3 categories have been proposed

Table 1. Demographic and Clinical Characteristics Among Those Undergoing HR-PCI

	All	HR-PCI (3)		HR-PCI (≥2)	P Value
	N=46 022	N=554	P Value	N=4414	
Demographics					
Age, y	65.7 (9.1)	75.0 (9.2)	<0.001	71.6 (10.0)	<0.001
Male	98%	98%	0.367	98%	0.072
White	83%	79%	0.010	81%	0.001
Hispanic	4%	5%	0.673	5%	0.264
Body mass index	30.6 (5.9)	27.2 (5.7)	< 0.001	29.0 (6.0)	<0.001
Comorbidities					
Congestive heart failure	25%	88%	<0.001	71%	<0.001
Chronic kidney disease	21%	62%	< 0.001	48%	<0.001
Chronic obstructive lung disease	24%	48%	<0.001	40%	<0.001
Cerebrovascular disease	17%	31%	< 0.001	27%	<0.001
Depression	32%	27%	0.008	28%	<0.001
Diabetes mellitus	49%	62%	<0.001	58%	<0.001
Hypertension	91%	95%	0.001	94%	<0.001
Hyperlipidemia	91%	91%	0.999	90%	0.635
Peripheral artery disease	20%	54%	<0.001	40%	<0.001
Previous myocardial infarction	37%	63%	< 0.001	53%	<0.001
Previous coronary intervention	42%	44%	0.322	43%	0.134
Previous stroke	9%	16%	< 0.001	15%	<0.001
Laboratory data					
Glomerular filtration rate			<0.001		<0.001
<30	5%	25%		17%	
30 to 60	19%	44%		36%	
60 to 90	52%	29%	ĺ	36%	
>90	25%	2%		10%	

Groups meeting 3 and ≥ 2 high-risk criteria are not mutually exclusive; therefore, separate testing with *P* values were performed comparing patients with 3 vs <3 high-risk criteria and ≥ 2 vs <2 high-risk criteria. Data presented as mean (SD) for continuous variables or percentages for categorical variables. HR-PCI indicates high-risk percutaneous coronary intervention.

as variables useful in defining HR-PCI: clinical comorbidities, ventricular hemodynamics, and coronary anatomical complexity.^{4,17,25} An ideal definition of HR-PCI should incorporate objective measures for each of these components, while maintaining applicability within existing registry infrastructure. With this in mind, standardized metrics have been developed to quantify patient risk based on pre-existing medical comorbidities, with the NCDR CathPCI Risk Score most commonly used.²¹ Similarly, left ventricular hemodynamics are frequently and imperfectly summarized with a singular measure of ejection fraction. Coronary anatomical complexity is challenging to characterize with a single measure, though complicated scores, such as the SYNTAX score, have been widely applied.^{26,27} The present analysis incorporates each of these objective measures, with coronary anatomical complexity estimated using a previously published and validated simplification of the SYNTAX score applicable for large data sets.²² The resulting cohort is a specific population with markers of risk in all 3 domains currently recognized by consensus documents as high-risk components for PCI.

The increasing medical and anatomical complexity of patients treated in the cardiac catheterization laboratory has led to an increase in HR-PCI. Previous research has demonstrated that the number and breadth of medical comorbidities among patients treated in the cardiac catheterization laboratory have markedly increased.²⁸ Similarly, data have demonstrated an expanding prevalence of patients with cardiomyopathy and reduced ejection fraction that may require coronary revascularization.²⁹ Finally, the anatomical complexity of patients treated with percutaneous means has also increased.^{22,30} This combination of factors may have contributed to an increase in the proportion of patients that

Table 2. Procedural Characteristics

	All	HR-PCI (3)		HR-PCI (≥2)		
	N=46 022	N=554	P Value	N=4414	P Value	
Length of stay, d	1 (1–3)	7 (3–12)	<0.001	4 (1–8)	<0.001	
Mechanical support	1%	16%	<0.001	8%	<0.001	
Status: elective	67%	21%	<0.001	41%	<0.001	
Indication			<0.001		<0.001	
Non–ST-segment–elevation MI	22%	56%		42%		
Unstable angina	26%	20%		21%		
Other	52%	24%		37%		
Vessels treated						
Left main coronary artery	1%	10%	<0.001	5%	<0.001	
Left anterior descending	47%	61%	<0.001	56%	<0.001	
Left circumflex	30%	35%	0.006	34%	<0.001	
Right coronary artery	36%	23%	<0.001	28%	<0.001	

Groups meeting 3 and ≥ 2 high-risk criteria are not mutually exclusive; therefore, separate testing with *P* values were performed comparing patients with 3 vs <3 high-risk criteria and ≥ 2 vs <2 high-risk criteria. Data presented as mean (SD) or median (interquartile range) for continuous variables or proportions for categorical variables. HR-PCI indicates high-risk percutaneous coronary intervention; MI, myocardial infarction.

are ineligible for surgical revascularization and thus proceed with percutaneous revascularization at an increased risk.³ The present analysis is consistent with these findings, given that the data suggest an increased proportion of patients that can be classified as high risk over time. The performance of highrisk interventions also appears to be clustered at specific sites within our integrated healthcare system, suggesting an efficient means to treat patients at specialized centers accustomed to performing higher-risk cases. These higherrisk cases may benefit from specialized technical skills and the availability of more-advanced mechanical support to facilitate intervention.

Mechanical support utilization increased with time for subsets of patients undergoing HR-PCI, albeit with significant variation across different sites. Previous consensus statements have suggested that mechanical support be considered for patients that meet high-risk criteria.¹⁷ With this in mind, previous research has demonstrated a concomitant increase in balloon pump use during elective intervention within the VA Healthcare System.³¹ The present analysis adds to these data, demonstrating a general trend toward increasing mechanical support among patients undergoing high-risk intervention. Furthermore, the data suggest that the use of novel mechanical support other than balloon pumps is increasing most rapidly, particularly in the most recent year analyzed. Despite the increased use of mechanical support, it remains rarely utilized in this cohort, with only 16% of HR-PCI being performed in a supported fashion. Perhaps the presence of significant peripheral artery disease in this cohort restricts the use of large-bore mechanical support. More important, however, there is a significant variation in the use of mechanical support across different facilities within an integrated healthcare system. Similar high-risk patients may experience a 2-fold difference in likelihood of receiving a supported intervention simply by changing procedure location. This heterogeneity may reflect local case mix, resource availability, as well as practice and referral patterns dependent on local expertise. In addition to this variability, the fact that only a small proportion of total high-risk interventions are done in a supported fashion underscores the need for further standardization of practice patterns. A larger randomized trial of mechanical support among high-risk patients would help elucidate the subpopulations that might be best served by this therapy, particularly in light of the growing number of high-risk procedures being performed.

Limitations

The present analysis should be interpreted in the context of several limitations. As alluded to, the definition of a high-risk coronary intervention is ambiguous. We attempted to create an objective definition using previously published consensus documents that highlight the various factors that may make a given intervention high risk. Furthermore, we have performed parallel analyses for patients that fulfilled 2 or 3 of the highrisk domains to provide both specific and sensitive definitions of a high-risk intervention. It is important to note that broader definitions encouraged by other professional societies may



Figure 3. Number of PCIs meeting 3 (**A**) or at least 2 (**B**) high-risk criteria, stratified by time. As shown, the raw number of high-risk cases significantly increased (P<0.001) in both cases over time, approaching 1.9% and 11.2% of the total case volume in the VA healthcare system in the last full calendar year analyzed, respectively. PCI indicates percutaneous coronary intervention; Q1, first quarter; VA, Veterans Affairs.

encapsulate patients that were not included in our cohort.³² Specifically, we could not accurately determine whether a patient with a previous bypass was undergoing intervention to

a high-risk lesion, and thus all patients with previous surgical revascularization who are often clinically and anatomically complex were excluded in order to generate highly specific



Figure 4. Temporal trends in the utilization of mechanical support for patients that met 3 (**A**) or at least 2 (**B**) of the criteria for a high-risk coronary intervention. As shown, the proportion has slightly increased in both cases being used in \approx 16% of patients that met all 3 criteria and 8% in those that met 2 criteria. The temporal trends suggest no significant increase in the use of mechanical support among those that met 3 criteria (*P*=0.193), though there was a linear increase among those that met 2 criteria (*P*=0.026). PCI indicates percutaneous coronary intervention; Q1, first quarter.



Figure 5. Temporal trends in major adverse events among patients that met 3 (A) or at least 2 (B) criteria for high-risk coronary intervention. As shown, there was no statistically significant difference in major adverse events relative to procedures performed at the start of the study.

results. The role of mechanical support in reducing the morbidity and mortality of high-risk coronary intervention is of intense interest. As an observational analysis, however, we are unable to compare the outcomes of patients that received mechanical support and those that did not because of significant unmeasured residual confounding. Because of the observational nature of this analysis, we are subject to further limitations, including possible misclassification of important variables and missing data, which, after exclusions, may lead us to understate the true high-risk volumes observed. Finally, the population and providers within this large integrated healthcare system may not reflect the sex or ethnic diversity found in other settings. Additional analyses in other data sets exploring other populations would be helpful in corroborating or refuting our findings.

Conclusions

The proportion of cases categorized as HR-PCI being performed has increased over time in a large integrated healthcare system, though with significant site-level variability. Despite consensus recommendations, the majority of these cases are performed without mechanical circulatory support, and use of support appears to be tied to site rather than patient characteristics. This discrepancy between recommendations and observed clinical practice highlights an opportunity to standardize practice patterns for patients undergoing HR-PCI.

Sources of Funding

The analytical work for this project was supported by an investigator-initiated grant from Abiomed, though the sponsor had no role in the analysis or presentation of the resulting data. Additional support for VA/CMS data is provided by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Health Services Research and Development, and VA Information Resource Center (Project Nos.: SDR 02-237 and 98-004).

Acknowledgments

This material is the result of work supported with resources and use of facilities at the Rocky Mountain Regional VA Medical Center. The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the US government.

Disclosures

Dr Armstrong is a consultant to Abbott Vascular, Boston Scientific, Cardiovascular Systems Incorporated, Intact Vascular, Medtronic, and Philips. Dr Waldo receives investigatorinitiated research support to the Denver Research Institute from Abiomed, Cardiovascular Systems Incorporated, and Merck Pharmaceuticals. The remaining authors have no disclosures to report.

References

- 1. Vora AN, Dai D, Gurm H, Amin AP, Messenger JC, Mahmud E, Mauri L, Wang TY, Roe MT, Curtis J, Patel MR, Dauerman HL, Peterson ED, Rao SV. Temporal trends in the risk profile of patients undergoing outpatient percutaneous coronary intervention: a report from the national cardiovascular data registry's CathPCI Registry. Circ Cardiovasc Interv. 2016;9:e003070.
- 2. Huang HW, Brent BN, Shaw RE. Trends in percutaneous versus surgical revascularization of unprotected left main coronary stenosis in the drug-eluting stent era: a report from the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR). Catheter Cardiovasc Interv. 2006;68:867-872.
- 3. Waldo SW, Secemsky EA, O'Brien C, Kennedy KF, Pomerantsev E, Sundt TM, McNulty EJ, Scirica BM, Yeh RW. Surgical ineligibility and mortality among patients with unprotected left main or multivessel coronary artery disease undergoing percutaneous coronary intervention. Circulation. 2014;130:2295-2301.
- 4. Rihal CS, Naidu SS, Givertz MM, Szeto WY, Burke JA, Kapur NK, Kern M, Garratt KN, Goldstein JA, Dimas V, Tu T; Society for Cardiovascular Angiography and Interventions (SCAI), Heart Failure Society of America (HFSA), Society of Thoracic Surgeons (STS), American Heart Association (AHA), and American College of Cardiology (ACC). 2015 SCAI/ACC/HFSA/ STS clinical expert consensus statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care: endorsed by the American Heart Assocation, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d'intervention. J Am Coll Cardiol. 2015;65:e7-e26.
- 5. Sandhu A, McCoy LA, Negi SI, Hameed I, Atri P, Al'Aref SJ, Curtis J, McNulty E, Anderson HV, Shroff A, Menegus M, Swaminathan RV, Gurm H, Messenger J, Wang T, Bradley SM. Use of mechanical circulatory support in patients undergoing percutaneous coronary intervention: insights from the National Cardiovascular Data Registry. Circulation. 2015;132:1243-1251.
- 6. Kirtane AJ, Doshi D, Leon MB, Lasala JM, Ohman EM, O'Neill WW, Shroff A, Cohen MG, Palacios IF, Beohar N, Uriel N, Kapur NK, Karmpaliotis D, Lombardi W, Dangas GD, Parikh MA, Stone GW, Moses JW. Treatment of higher-risk patients with an indication for revascularization: evolution within the field of contemporary percutaneous coronary intervention. Circulation. 2016;134:422-431.
- 7. Jensen LO, Kaltoft A, Thayssen P, Tilsted HH, Christiansen EH, Mikkelsen KV, Maeng M, Hansen KN, Villadsen AB, Madsen M, Lassen JF, Pedersen KE, Thuesen L. Outcome in high risk patients with unprotected left main coronary artery stenosis treated with percutaneous coronary intervention. Catheter Cardiovasc Interv. 2010;75:101-108.
- Puricel S, Adorjan P, Oberhänsli M, Stauffer JC, Moschovitis A, Vogel R, Goy J-J, Müller O, Eeckhout E, Togni M, Wenaweser P, Meier B, Windecker S, Cook S. Clinical outcomes after PCI for acute coronary syndrome in unprotected left main coronary artery disease: insights from the Swiss Acute Left Main Coronary Vessel Percutaneous Management (SALVage) study. EuroIntervention. 2011;7:697-704.
- 9. Patel MR, Smalling RW, Thiele H, Barnhart HX, Zhou Y, Chandra P, Chew D, Cohen M, French J, Perera D, Ohman EM. Intra-aortic balloon counterpulsation and infarct size in patients with acute anterior myocardial infarction without shock: the CRISP AMI randomized trial. JAMA. 2011;306:1329-1337.
- 10. Curtis JP, Rathore SS, Wang Y, Chen J, Nallamothu BK, Krumholz HM. Use and effectiveness of intra-aortic balloon pumps among patients undergoing high risk percutaneous coronary intervention: insights from the National Cardiovascular Data Registry. Circ Cardiovasc Qual Outcomes. 2012;5:21-30.
- 11. Dixon SR, Henriques JPS, Mauri L, Sjauw K, Civitello A, Kar B, Loyalka P, Resnic FS, Teirstein P, Makkar R, Palacios IF, Collins M, Moses J, Benali K, O'Neill WW. A prospective feasibility trial investigating the use of the Impella 2.5 system in patients undergoing high-risk percutaneous coronary intervention (The PROTECT | Trial): initial U.S. experience. JACC Cardiovasc Interv. 2009;2:91-96.
- 12. Sjauw KD, Konorza T, Erbel R, Danna PL, Viecca M, Minden H-H, Butter C, Engstrøm T, Hassager C, Machado FP, Pedrazzini G, Wagner DR, Schamberger R, Kerber S, Mathey DG, Schofer J, Engström AE, Henriques JPS. Supported high-risk percutaneous coronary intervention with the Impella 2.5 device the Europella registry. J Am Coll Cardiol. 2009;54:2430-2434.
- 13. O'Neill WW, Kleiman NS, Moses J, Henriques JPS, Dixon S, Massaro J, Palacios I, Maini B, Mulukutla S, Dzavík V, Popma J, Douglas PS, Ohman M. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. *Circulation*. 2012;126:1717–1727.
- 14. Schwartz BG, Ludeman DJ, Mayeda GS, Kloner RA, Economides C, Burstein S. High-risk percutaneous coronary intervention with the TandemHeart and Impella devices: a single-center experience. J Invasive Cardiol. 2011;23:417-424.

- 15. Alli OO, Singh IM, Holmes DR, Pulido JN, Park SJ, Rihal CS. Percutaneous left ventricular assist device with TandemHeart for high-risk percutaneous coronary intervention: the Mayo Clinic experience. Catheter Cardiovasc Interv.
- 16. Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, Chambers CE, Ellis SG, Guyton RA, Hollenberg SM, Khot UN, Lange RA, Mauri L, Mehran R, Moussa ID, Mukherjee D, Nallamothu BK, Ting HH. 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. 2011;124:e574-e651.

2012;80:728-734.

- 17. Atkinson TM, Ohman EM, O'Neill WW, Rab T, Cigarroa JE. A practical approach to mechanical circulatory support in patients undergoing percutaneous coronary intervention: an interventional perspective. JACC Cardiovasc Interv. 2016;9:871-883.
- 18. Maddox TM, Plomondon ME, Petrich M, Tsai TT, Gethoffer H, Noonan G, Gillespie B, Box T, Fihn SD, Jesse RL, Rumsfeld JS. A national clinical quality program for Veterans Affairs catheterization laboratories (from the Veterans Affairs clinical assessment, reporting, and tracking program). Am J Cardiol. 2014;114:1750-1757.
- 19. Brindis RG, Fitzgerald S, Anderson HV, Shaw RE, Weintraub WS, Williams JF. The American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR): building a national clinical data repository. J Am Coll Cardiol. 2001;37:2240–2245.
- 20. Byrd JB, Vigen R, Plomondon ME, Rumsfeld JS, Box TL, Fihn SD, Maddox TM. Data quality of an electronic health record tool to support VA cardiac catheterization laboratory quality improvement: the VA Clinical Assessment, Reporting, and Tracking System for Cath Labs (CART) program. Am Heart J. 2013;165:434-440.
- 21. Peterson ED, Dai D, DeLong ER, Brennan JM, Singh M, Rao SV, Shaw RE, Roe MT, Ho KKL, Klein LW, Krone RJ, Weintraub WS, Brindis RG, Rumsfeld JS, Spertus JA; NCDR Registry Participants. Contemporary mortality risk prediction for percutaneous coronary intervention: results from 588,398 procedures in the National Cardiovascular Data Registry. J Am Coll Cardiol. 2010:55:1923-1932.
- 22. Valle JA, Glorioso TJ, Bricker R, Barón AE, Armstrong EJ, Bhatt DL, Rao SV, Plomondon ME, Serruys PW, Keppetein AP, Sabik JF, Dressler O, Stone GW, Waldo SW. Association of coronary anatomical complexity with clinical outcomes after percutaneous or surgical revascularization in the veterans affairs clinical assessment reporting and tracking program. JAMA Cardiol. 2019 Jun 26. doi: 10.1001/jamacardio.2019.1923. [Epub ahead of print]. PMID is 31241721.
- 23. US Department of Veterans Affairs, VIReC Home [Internet], Available at: http://www.virec.research.va.gov/index.htm. Accessed July 27, 2016.
- 24. Glorioso TJ, Grunwald GK, Ho PM, Maddox TM. Reference effect measures for quantifying, comparing and visualizing variation from random and fixed effects in non-normal multilevel models, with applications to site variation in medical procedure use and outcomes. BMC Med Res Methodol. 2018;18:74.
- 25. Myat A, Patel N, Tehrani S, Banning AP, Redwood SR, Bhatt DL. Percutaneous circulatory assist devices for high-risk coronary intervention. JACC Cardiovasc Interv. 2015:8:229-244.
- 26. Sianos G, Morel MA, Kappetein AP, Morice M-C, Colombo A, Dawkins K, van den Brand M, Van Dyck N, Russell ME, Mohr FW, Serruys PW. The SYNTAX Score: an angiographic tool grading the complexity of coronary artery disease. EuroIntervention. 2005;1:219-227.
- 27. Serruys PW, Morice MC, Kappetein AP, Colombo A, Holmes DR, Mack MJ, Ståhle E, Feldman TE, van den Brand M, Bass EJ, Van Dyck N, Leadley K, Dawkins KD, Mohr FW; SYNTAX Investigators. ercutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. *N Engl J Med.* 2009;360:961–972.
- 28. Waldo SW, Gokhale M, O'Donnell CI, Plomondon ME, Valle JA, Armstrong EJ, Schofield R, Fihn SD, Rumsfeld JS, Maddox TM. Temporal trends in coronary angiography and percutaneous coronary intervention: insights from the VA CART program. JACC Cardiovasc Interv. 2018;11:879-888.
- 29. Conrad N, Judge A, Tran J, Mohseni H, Hedgecott D, Crespillo AP, Allison M, Hemingway H, Cleland JG, McMurray JJV, Rahimi K. Temporal trends and patterns in heart failure incidence: a population-based study of 4 million individuals (accest 2019:001570-500 individuals. Lancet. 2018;391:572–580.
- 30. Go AS, Mozaffarian D, Roger VL, Benjamin EJ, Berry JD, Blaha MJ, Dai S, Ford ES, Fox CS, Franco S, Fullerton HJ, Gillespie C, Hailpern SM, Heit JA, Howard VJ, Huffman MD, Judd SE, Kissela BM, Kittner SJ, Lackland DT, Lichtman JH, Lisabeth LD, Mackey RH, Magid DJ, Marcus GM, Marelli A, Matchar DB, McGuire DK, Mohler ER, Moy CS, Mussolino ME, Neumar RW, Nichol G, Pandey DK, Paynter NP, Reeves MJ, Sorlie PD, Stein J, Towfighi A, Turan TN, Virani SS, Wong ND, Woo D, Turner MB; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Executive summary: heart

disease and stroke statistics—2014 update: a report from the American Heart Association. *Circulation*. 2014;129:399–410.

- Jawaid O, Stanislawski M, Bricker R, Plomondon ME, Grunwald GK, Valle JA, Armstrong EJ, Waldo SW. Contemporary use of intra-aortic balloon pumps during percutaneous coronary intervention: insights from the Veterans Affairs Clinical Assessment, Reporting, and Tracking program. *Coron Artery Dis.* 2019;30:44–50.
- 32. Chieffo A, Burzotta F, Pappalardo F, Briguori C, Garbo R, Masiero G, Nicolini E, Ribichini F, Trani C, Álvarez BC, Leor OR, Moreno R, Santos R, Fiarresga A, Silveira JB, de Prado AP, Musumeci G, Esposito G, Tarantini G. Clinical expert consensus document on the use of percutaneous left ventricular assist support devices during complex high-risk indicated PCI: Italian Society of Interventional Cardiology Working Group Endorsed by Spanish and Portuguese Interventional Cardiology Societies. Int J Cardiol. 2019;293:84–90.

SUPPLEMENTAL MATERIAL

Procedure	Codes
Rehospitalization for Myocardial Infarction	
ICD-9	410.00, 410.01, 410.10, 410.11, 410.20, 410.21, 410.30,
	410.31, 410.40, 410.41, 410.50, 410.51, 410.60, 410.61,
	410.70, 410.71, 410.80, 410.81, 410.90, 410.91
ICD-10	121.01, 121.02, 121.09, 121.11, 121.19, 121.21, 121.29, 121.3,
	121.4, 122.0, 122.1, 122.2, 122.8, 122.9
Rehospitalization for Stroke	
ICD-9	346.60, 346.61, 346.62, 346.63, 431, 433.01, 433.11, 433.21,
	433.31, 433.81, 433.91, 434.01, 434.11, 434.91, 997.0
ICD-10	G43.601, G43.609, G43.611, G43.619, I61.0, I61.1, I61.2, I61.3,
	161.4, 161.5, 161.6, 161.8, 161.9, 163.00, 163.011, 163.012,
	163.013, 163.019, 163.02, 163.031, 163.032, 163.033, 163.039,
	163.09, 163.10, 163.111, 163.112, 163.113, 163.119, 163.12,
	163.131, 163.132, 163.133, 163.139, 163.19, 163.20, 163.211,
	163.212, 163.213, 163.219, 163.22, 163.231, 163.232, 163.233,
	163.239, 163.29, 163.30, 163.311, 163.312, 163.313, 163.319,
	163.321, 163.322, 163.323, 163.329, 163.331, 163.332, 163.333,
	163.339, 163.341, 163.342, 163.343, 163.349, 163.39, 163.40,

 Table S1. Administrative codes used to identify procedures and readmission.

I63.411, I63.412, I63.413, I63.419, I63.421, I63.422, I63.423,
I63.429, I63.431, I63.432, I63.433, I63.439, I63.441, I63.442,
I63.443, I63.449, I63.49, I63.50, I63.511, I63.512, I63.513,
I63.519, I63.521, I63.522, I63.523, I63.529, I63.531, I63.532,
I63.533, I63.539, I63.541, I63.542, I63.543, I63.549, I63.59,
I63.6, I63.8, I63.9, I97.810, I97.811, I97.820, I97.821

Figure S1. Types of mechanical support devices employed for high-risk coronary intervention using three (A) or two (B) criteria to define a case as high-risk.



Figure S2. Temporal trends of the probability of mechanical support device utilization during high-risk coronary intervention using three (A) or two (B) criteria to define a case as high-risk. There was a linear increase in the utilization of mechanical support other than a balloon pump among patients meeting three (P=0.001) and at least two (P=<0.001) criteria for a high-risk intervention.

