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Original Research

Influence of Major Adverse Events on Procedural Selection for Percutaneous Coronary Intervention: Insights From the Veterans Affairs Clinical Assessment Reporting and Tracking Program

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ABSTRACT

Background: Public reporting of percutaneous coronary intervention (PCI) outcomes has been associated with risk-averse attitudes, and pressure to avoid negative outcomes may hinder the care of high-risk patients referred for PCI in public reporting environments. It is unknown whether the occurrence of PCI-related major adverse events (MAEs) influences future case selection in nonpublic reporting environments. Here, we describe trends in PCI case selection among patients undergoing coronary angiography following MAEs in Veterans Affairs (VA) cardiac catheterization laboratories participating in a mandatory internal quality improvement program without public reporting of outcomes.

Methods: Patients who underwent coronary angiography between October 1, 2010, and September 30, 2018, were identified and stratified by VA 30-day PCI mortality risk. The association between MAEs and changes in the proportion of patients proceeding from coronary angiography to PCI within 14 days was assessed.

Results: A total of 251,526 patients and 913 MAEs were included in the analysis. For each prespecified time period of 1, 2, and 4 weeks following an MAE, there were no significant changes in the proportion of patients undergoing coronary angiography who proceeded to PCI within 14 days for the overall cohort and for each tercile of VA 30-day PCI mortality risk.

Conclusions: There were no deviations from routine PCI referral practices following MAEs in this analysis of VA cardiac catheterization laboratories. Nonpublic reporting environments and quality improvement programs may be influential in mitigating PCI risk-aversion behaviors.

Introduction

Risk-aversion attitudes and practice patterns are prevalent among interventional cardiologists.[1-4] The public reporting of the outcomes of percutaneous coronary intervention (PCI) is mandated in several states (ie, Massachusetts, New Jersey, New York, Pennsylvania, and Washington) and has been associated with decreased in-hospital mortality following PCI.[5,6] However, public reporting has also been associated with the PCI avoidance among physicians treating ST-elevation myocardial infarction (MI), cardiogenic shock, or cardiac arrest and increased mortality among patients who do not undergo intervention.[6-11] Thus, risk-averse attitudes may be beneficial in limiting risk in patients and improving procedural outcomes but may hinder care among high-risk patients with the most to gain from a potentially life-saving intervention.[12-14] These data have engendered controversy over the benefits of public reporting.[15-20] Surveys of interventional cardiologists have suggested that operators practicing in public reporting environments perceive greater pressure to avoid PCI because of the risk of negative outcomes compared with those practicing in nonpublic reporting environments.[3,4,21] This raises an important question: does the occurrence of a PCI-related major adverse event (MAE) have the same influence on future case selection as the specter of public reporting of such an event?

Abbreviations: CABG, coronary artery bypass grafting; CART, Clinical Assessment, Reporting, and Tracking; GEE, generalized estimating equation; MAE, major adverse event; NCDR, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between PCI With TAXUS and Cardiac Surgery; VA, Veterans Affairs.

Keywords: adverse events; outcome reporting; patient selection; percutaneous coronary intervention; quality.

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Cardiac catheterization laboratories in the Veterans Affairs (VA) Healthcare System, the largest integrated health care system in the United States, participate in the Clinical Assessment Reporting and Tracking (CART) Program, a mandatory, internal quality improvement initiative that does not publicly report outcomes.[22-24] Thus, any changes in case selection for PCI following an MAE at VA facilities would likely represent internal pressure to alter clinical behavior in response to perceived risk, independent of public influence. Here, we describe trends in PCI case selection following MAEs in the VA Healthcare System.

Materials and methods

Population

The VA CART Program is a nationally mandated quality and safety program that captures and compiles standardized patient and procedural data on invasive cardiac procedures performed throughout the VA Healthcare System.[22] The data elements surveyed are derived from previously established definitions provided by the National Cardiovascular Data Registry, and the dataset is independently assessed for accuracy and validity on a routine basis.[22,23] This study identified all patients who underwent coronary angiography in the VA Healthcare System from October 1, 2010, to September 30, 2018. Patients were excluded if their VA 30-day PCI mortality risk could not be calculated, coronary angiography was performed at a site that did not perform PCI, the patient had normal coronary anatomy but proceeded to undergo PCI within 14 days, or patient demographic or clinical data were missing (Figure 1 and Supplemental Table S1).[25] This study was approved by the Colorado Multiple Institutions Review Board, with a waiver of informed consent.

Data collection

Data on patient and procedural characteristics were obtained from CART. Facility characteristics, including VA administrative region, academic affiliation, on-site cardiac surgery, and ability to provide percutaneous left ventricular assist device support, were also described. The 30-day PCI mortality risk was calculated as previously described, and incorporated clinical presentation (eg, ST-elevation MI, cardiogenic shock, and cardiac arrest), procedure status (eg, elective, urgent, emergent, and salvage), and anatomic complexity (ie, VA SYNTAX [Synergy Between PCI With TAXUS and Cardiac Surgery] score), in addition to patient demographics, comorbidities, and laboratory studies.[25] MAEs were defined as periprocedural death, periprocedural stroke, or unplanned coronary artery bypass graft surgery, events that are required to be reported to the CART Program. The proportion of patients proceeding from angiography to PCI, defined as PCI within 14 days of the index angiography, was described. In January 2011, CART began a peer review quality improvement process in which MAEs were reviewed monthly and graded as level 1, in which most operators performed similarly; level 2, in which some operators performed differently; and level 3, in which most operators performed differently.[24] For MAEs with reviews available, peer review scores were obtained. The remaining MAEs without peer review documentation were assigned a "missing" review score.

Statistical analysis

Baseline patient, procedural, anatomic, and facility characteristics were determined for the overall cohort and stratified by subsequent PCI status. Categorical variables were reported as counts and percentages and continuous variables as medians and interquartile ranges. Standardized differences were calculated, and a threshold of $\geq$10% was used to indicate imbalance between the groups.

The primary outcome was change in the proportion of patients proceeding from coronary angiography to PCI within 14 days following a facility MAE. The study aimed to assess risk aversion after MAEs; however, the time period during which the risk-averting behavior might occur was unknown. Thus, plausible time periods of 1, 2, and 4 weeks were selected a priori. A modified Poisson generalized estimating equation model with adjustment for multiple comparisons using the Benjamini-Hochberg method was used to estimate the risk ratio of proceeding to PCI following an MAE.[26-28] The base-modified Poisson model included adjustment for patient, procedural, anatomic, and facility characteristics; adjustment for continuous time using the date of coronary angiography; peer review rating of MAEs; and missing peer review rating. The results were stratified by the tercile of VA 30-day mortality risk: low, <0.12%; intermediate, 0.12%-0.51%; and high, >0.52%.[25] Generalized estimating equation

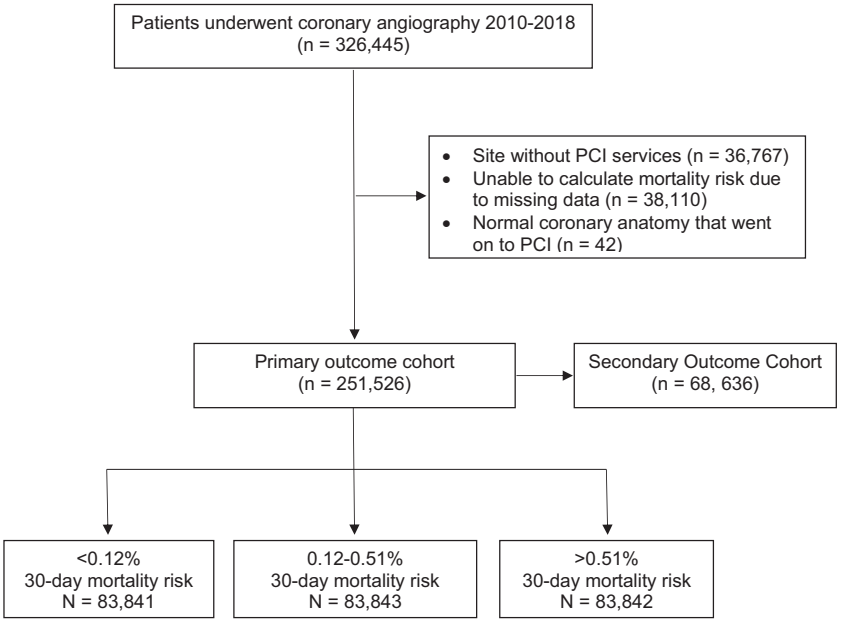


Figure 1. Flow diagram of inclusion and exclusion criteria for the analytic cohorts. A summary of the missing data elements precluding calculation of the Veterans Affairs 30-day mortality risk score is presented in Supplemental Table S1. PCI, percutaneous coronary intervention.

Table 1. Patient and procedural characteristics.

	Overall (N = 251,526)	No PCI (n = 182,890)	PCI (n = 68,636)	Standardized difference
Demographics				
Age, y	66.2 (61.1-71.3)	66.1 (60.9-71.2)	66.4 (61.5-71.6)	6.9
Male	244,261 (97.1)	176,870 (96.7)	67,391 (98.2)	9.4
Race				11.0
White	202,249 (80.4)	145,080 (79.3)	57,169 (83.3)	
Black	43,395 (17.3)	33,562 (18.4)	9833 (14.3)	
Other	5882 (2.3)	4248 (2.3)	1634 (2.4)	
Hispanic ethnicity	13,175 (5.2)	9726 (5.3)	3449 (5.0)	1.3
Body mass index, kg/m^2	29.9 (26.4-34.2)	30.0 (26.4-34.3)	29.8 (26.4-33.9)	3.8
Comorbidities				
Prior CA	127,253 (50.6)	87,608 (47.9)	39,645 (57.8)	19.8
Prior MI	92,071 (36.6)	61,800 (33.8)	30,271 (44.1)	21.3
Prior PCI	89,542 (35.7)	56,591 (30.9)	32,951 (48.0)	35.5
Prior CABG	58,432 (23.2)	38,518 (21.2)	19,914 (29.0)	18.4
Atrial fibrillation	43,256 (17.2)	33,905 (18.5)	9,351 (13.6)	13.4
CVD	46,735 (18.6)	33,208 (18.2)	13,527 (19.7)	4.0
Diabetes	125,218 (49.8)	89,481 (48.9)	35,737 (52.1)	6.3
Heart failure	82,062 (32.6)	62,949 (34.4)	19,113 (27.8)	14.2
Hypertension	227,628 (90.5)	164,800 (90.1)	62,828 (91.5)	5.0
Hyperlipidemia	223,013 (88.7)	160,203 (87.6)	62,810 (91.5)	12.8
PAD	53,491 (21.3)	37,795 (20.7)	15,696 (22.9)	5.3
Chronic kidney disease	58,965 (23.4)	42,795 (23.4)	16,170 (23.6)	0.4
Chronic lung disease	76,761 (30.5)	56,887 (31.1)	19,874 (29.0)	4.7
Tobacco use	166,589 (66.2)	120,433 (65.8)	46,156 (67.2)	3.0
Depression	83,997 (33.4)	61,748 (33.8)	22,249 (32.4)	2.9
PTSD	50,005 (19.9)	37,004 (20.2)	13,001 (18.9)	3.3
Procedural characteristics				
Presentation				19.2
Atypical chest pain	30,329 (12.1)	24,375 (13.3)	5954 (8.7)	
Stable angina	54,613 (21.7)	38,121 (20.8)	16,492 (24.0)	
Unstable angina	34,721 (13.8)	22,630 (12.4)	12,091 (17.6)	
NSTEMI	29,134 (11.6)	15,427 (8.4)	13,707 (20.0)	
STEMI	3961 (1.6)	1125 (0.6)	2836 (4.1)	
Valve disease	15,200 (6.0)	14,579 (8.0)	621 (0.9)	
Other[a]	53,421 (21.1)	45,018 (24.6)	8403 (12.2)	
Unknown	30,147 (12.0)	21,615 (11.8)	8532 (12.4)	
Urgency				14.4
Elective	181,479 (72.1)	140,590 (76.9)	40,889 (59.6)	
Urgent	59,959 (23.8)	37,060 (20.3)	22,899 (33.4)	
Emergent	6914 (2.7)	2362 (1.3)	4552 (6.6)	
Salvage	101 (0.0)	24 (0.0)	77 (0.1)	
Unknown	3073 (1.2)	2854 (1.6)	219 (0.3)	
VA 30-day PCI mortality risk	0.26% (0.08-0.75)	0.21% (0.07-0.65)	0.39% (0.16-1.1)	17.6
Coronary anatomy				20.2
1 vessel	56,904 (22.6)	28,575 (15.6)	28,329 (41.3)	
2 vessels	42,025 (16.7)	22,664 (12.4)	19,361 (28.2)	
3 vessels or LM	60,465 (24.0)	42,649 (23.3)	17,816 (26.0)	
Nonobstructive	64,137 (25.5)	61,433 (33.6)	2704 (3.9)	
Normal	25,961 (10.3)	25,961 (14.2)	0 (0)	
Other	633 (0.3)	531 (0.3)	102 (0.1)	
CTO	70,548 (28.0)	46,664 (25.5)	23,884 (34.8)	20.3
Cardiogenic shock	881 (0.4)	478 (0.3)	403 (0.6)	5.0
VA SYNTAX score	3 (0-13)	1 (0-12)	7 (2-15)	30.8

All numbers expressed as n (%) or median (IQR).

CA, coronary angiography; CABG, coronary artery bypass grafting; CTO, chronic total occlusion; CVD, cerebrovascular disease; LM, left main; MI, myocardial infarction; NSTEMI, non–ST-elevation myocardial infarction; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; PTSD, posttraumatic stress disorder; STEMI, ST-elevation myocardial infarction; SYNTAX, Synergy Between PCI With TAXUS and Cardiac Surgery; VA, Veterans Affairs.

[a] The other presentation types include aortic valve disease, arrhythmia, asymptomatic ischemia, cardiac tamponade, cardiomyopathy, congenital heart disease, heart failure, mitral valve disease, positive functional study, preoperative noncardiac surgery, pulmonary hypertension, cardiac transplant, syncope, transplant evaluation, and other.

methods were used to account for clustering at the site level. The risk ratios, 95% CIs, unadjusted and Benjamini-Hochberg adjusted *P* values were calculated for each analyzed time period from MAE to coronary angiography. Robust sandwich estimator methods were used to calculate the standard errors and 95% CIs. Adjusted *P* values $<.05$ were considered statistically significant.

The secondary outcome was the number of days from coronary angiography to PCI. To determine the impact of MAEs on the secondary outcome, the analytic cohort was restricted to patients who underwent PCI within 14 days of coronary angiography. A zero-inflated Poisson model was employed because the majority of PCIs included in the secondary outcome analysis occurred on the same day as coronary angiography.[29] Covariate adjustments were similar to those described for the primary outcome analyses. The number of days from MAE to coronary angiography was included as an adjustment variable if the time from MAE to angiography was <7 days.

All data were compiled using SAS software, version 9.4 (SAS Institute). Statistical, descriptive, and graphical analyses were performed using R, version 3.5.3.

Table 2. Facility characteristics.

	Overall (N = 251,526)	No PCI (n = 182,890)	PCI (n = 68,636)	Standardized difference
Academic affiliation	239,338 (95.2)	174,221 (95.3)	65,117 (94.9)	1.8
On-site cardiac surgery	178,050 (70.8)	129,922 (71.0)	48,128 (70.1)	2.0
Non-IABP MCS	172,172 (68.5)	123,561 (67.6)	48,611 (70.8)	7.1
VA administrative region				10.9
Continental	45,848 (18.2)	31,500 (17.2)	14,348 (20.9)	
Midwest	61,952 (24.6)	44,774 (24.5)	17,178 (25.0)	
North Atlantic	50,330 (20.0)	36,655 (20.0)	13,675 (19.9)	
Pacific	37,847 (15.0)	28,353 (15.5)	9,494 (13.8)	
Southeast	55,549 (22.1)	41,608 (22.8)	13,941 (20.3)	

All numbers expressed as n (%).
IABP, intra-aortic balloon pump; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention; VA, veterans affairs.

Results

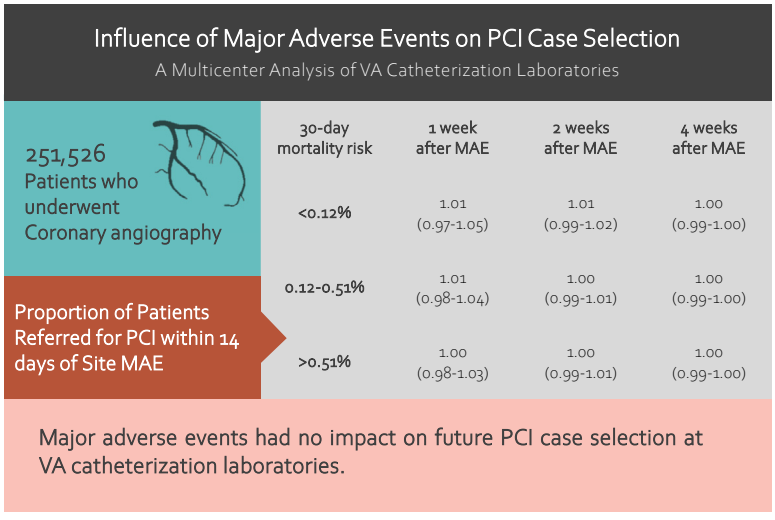
A total of 251,526 patients who underwent coronary angiography were included in the analysis (Figure 1). Of these patients, 3.9% (n = 9702), 7.5% (n = 18,774), and 14.0% (n = 35,219) underwent coronary angiography within 1, 2, or 4 weeks of an MAE, respectively. Furthermore, 27.3% (n = 68,636) of the study population subsequently underwent PCI within 14 days of the index angiography. The patient and procedural characteristics of the overall cohort and the same stratified by subsequent PCI status are presented in Table 1. Patients proceeding to PCI had higher rates of prior MI and prior PCI, lower rates of congestive heart failure, more frequently had multivessel coronary artery disease, and more frequently presented with acute coronary syndromes. The facility characteristics for patients who did and did not proceed to PCI within 14 days and those of the overall cohort are presented in Table 2. Patients who subsequently underwent PCI were more likely to be treated by facilities located in the Continental and Midwest VA administrative regions of the United States. There were no significant differences in the availability of on-site cardiac surgery services, capability to provide percutaneous mechanical circulatory support, or affiliation with an academic center among clinical sites.

The primary outcome cohort was stratified by tercile of VA 30-day PCI mortality risk (Central Illustration). Among patients who underwent angiography, 16.0% in the lowest risk tercile went on to PCI, as did 31.1% in the intermediate risk tercile, and 34.8% in the highest risk tercile. A total of 913 MAEs (ie, intraprocedural death, intraprocedural stroke, and unplanned coronary artery bypass graft) occurred during the study period. Peer review scores were available for 231 MAEs: 10 received a rating of level 3, 31 received a rating of level 2, and 191 received a rating of level 1. For each prespecified time period of 1, 2, and 4 weeks following an MAE, there were no significant changes in the proportion of patients undergoing coronary angiography who proceeded to PCI within 14 days for the overall cohort and for each tercile of 30-day PCI mortality risk after adjustment for MAE peer review rating and patient, procedural, and facility characteristics (Table 3).

For the secondary outcome, the cohort was restricted to the 68,636 patients undergoing coronary angiography who subsequently underwent PCI within 14 days. Of these patients, the majority (89.2%) underwent PCI on the same day as coronary angiography, 2.1% underwent PCI on the next day, and the remainder (8.7%) underwent PCI between 2 and 14 days after coronary angiography. There were no absolute differences in the proportion of patients who subsequently underwent PCI on the same day (88.9 vs 89.2%; $P = .60$), on the next day (1.8 vs 2.1%; $P = .26$), or between 2 and 14 days (11.1 vs 10.8%; $P = .24$) between the subgroups with and without an MAE in the week preceding coronary angiography. After adjustment, there was no significant impact of MAEs within 1 week of coronary angiography on the number of days between coronary angiography and subsequent PCI (risk ratio, 0.99; 95% CI, 0.97-1.01; $P = .37$).

Discussion

This analysis evaluated the influence of MAEs on case selection and risk tolerance at PCI facilities in the largest integrated health care system in the United States, the VA Healthcare System. The impact of an MAE occurring between 1 and 4 weeks prior to coronary angiography on



Central Illustration. Influence of major adverse events on patient case selection for percutaneous coronary intervention. MAE, major adverse event, PCI, percutaneous coronary intervention; VA, veterans affairs.

Table 3. Association of major adverse events with proceeding to percutaneous coronary intervention within 14 days of coronary angiography, stratified by tercile of veterans affairs 30-day percutaneous coronary intervention mortality risk.

	1 Week after MAE	2 Weeks after MAE	4 Weeks after MAE
Overall cohort			
Risk ratio (95% CI)	1.01 (0.99-1.03)	1.010 (0.99-1.01)	1.00 (0.99-1.00)
Unadjusted *P* value	.80	.42	.34
Adjusted *P* value	.80	.63	.63
<0.12% 30-d mortality risk			
Risk ratio (95% CI)	1.01 (0.97-1.05)	1.01 (0.99-1.02)	1.00 (0.99-1.00)
Unadjusted *P* value	.49	.81	.66
Adjusted *P* value	.81	.81	.81
0.12%-0.51% 30-d mortality risk			
Risk ratio (95% CI)	1.01 (0.98-1.04)	1.00 (0.99-1.01)	1.00 (0.99-1.00)
Unadjusted *P* value	.69	.34	.42
Adjusted *P* value	.69	.63	.63
>0.51% 30-d mortality risk			
Risk ratio (95% CI)	1.00 (0.98-1.03)	1.00 (0.99-1.01)	1.00 (0.99-1.00)
Unadjusted *P* value	.50	.36	.41
Adjusted *P* value	.50	.50	.50

Thirty-day mortality risk categories refer to the estimated veterans affairs 30-day percutaneous coronary intervention mortality risk score. The adjusted *P* values for multiple comparisons generated using the Benjamini-Hochberg method are presented.
MAE, major adverse event.

subsequent referral for PCI within 14 days was evaluated with adjustment for peer review rating of MAEs as well as patient, procedural, and facility characteristics. No significant deviations from routine PCI referral practices were observed following an MAE among >250,000 analyzed procedures. This observation was consistent when stratified by the estimated VA 30-day PCI mortality risk. These data suggest that there is no significant risk aversion for PCI following MAEs in the VA Healthcare System.

Prior analyses have suggested that MAEs can influence the attitudes of physicians and peers regarding higher-risk case selection even if such patients stand to benefit the most.[4,6-10,30] However, these data were mainly drawn from facilities that report outcomes publicly, suggesting that harm to the operator's or facility's reputation is the primary motivator for these negative attitudes.[4,12,21] Limited data have suggested that risk-avoidant attitudes persist in settings without public reporting, perhaps because of the influence of indirect reporting by registries and other mechanisms on public perception and media rankings.[30] The present study found no association between facility MAEs and subsequent referral for PCI among patients who underwent coronary angiography in the VA Healthcare System. Although the operators' attitudes were not directly assessed in this analysis, the surrogate end points of which cases were selected for PCI and number of days to PCI did not change at any time after an MAE, suggesting that pressures to avoid risk may not significantly influence decision making at VA catheterization laboratories.

Public reporting has been shown to be associated with procedural risk aversion, and interventional cardiologists have expressed significant mistrust in currently employed public reporting systems.[3,17,21] The negative opinion of public reporting may arise from criticisms of the analytic methods used and the clinical outcomes reported.[31,32] In contrast, the internal nonpublic reporting environment developed by the CART Program employs a peer review process wherein operators grade MAEs based on whether they would or would not have performed similarly. Operator surveys have suggested that these practices are less likely to engender a perception of punitive scrutiny and allow for conveyed clinical outcomes to be received as constructive and actionable feedback for quality improvement.[21] The current study confirmed these reports and showed that internally reported MAEs are not associated with risk-aversion behaviors by VA operators, regardless of the peer rating of the MAE or procedural risk of the patient referred for intervention. However, further study is needed to determine whether nonpublic reporting environments and internal quality improvement mechanisms, such as those developed by CART, have additive effects in counterbalancing negative attitudes toward case selection associated with MAEs.

Ultimately, interventional cardiologists must provide timely and appropriate procedural care to patients in whom the potential harms are outweighed by the anticipated benefits. Quality metrics and reporting standards must be aligned with these goals to deter risk-avoidant behaviors and allow patients to benefit from appropriate and indicated procedural care. Various interventions can be considered to achieve this goal and improve interventional quality. A collaborative model of data sharing and multidisciplinary peer education should be encouraged.[20] Outcomes should be reported at the hospital level to acknowledge that health care quality and patient outcomes extend beyond the procedural suite.[33] Performance metrics beyond mortality should be incorporated into assessments of procedural care to better reflect the overall low risk of death associated with coronary interventions and the inconsistent association between procedural quality and mortality.[2,31,32,34,35] Targeted metrics would highlight myriad opportunities to enhance interventional quality via reductions in inappropriate PCI; more frequent use of radial artery access, coronary physiologic assessments, and intravascular imaging; and increased adherence to postprocedure medical therapy.[36-42] Finally, practice profiles of interventional cardiologists that include data on annual volumes and case acuity could be used to identify goals for the longitudinal growth and maintenance of operators' technical skills and the distribution of patients to operators with the appropriate expertise to ensure optimal patient care.[43,44] The current study underscores the potential of novel quality initiatives and outcome reporting mechanisms, such as the CART Program, to enhance patient care by promoting excellence in all aspects of interventional cardiology care.

Limitations

The analysis must be interpreted within the context of its limitations. First, these findings were derived from the nationally integrated VA Healthcare System and may not be representative of or applicable to the experience of other centers. However, various national and regional quality improvement programs collect data on MAEs and could be leveraged to offer similar services by integrating quality improvement on a broader scale.[22,45-48] Second, case selection by operators is multifactorial, and unmeasured factors beyond the clinical and anatomic characteristics addressed in this study may counterbalance or amplify risk aversion. Factors such as operator workload and reimbursement may impact decision making but are less likely to be influential within the capitated structure of the VA Healthcare System. Third, the analysis evaluated the proportion of patients who underwent PCI after coronary angiography at VA facilities and did not account for patients who were

transferred to non-VA sites for PCI. This may have introduced a bias if PCI risk aversion led to transfers to non-VA facilities. Fourth, the analysis assumed that risk-aversion behaviors might occur during the plausible time periods of 1, 2, or 4 weeks after an MAE. It is possible that changes in case selection for PCI occurred at longer periods after an MAE and were not captured in the analysis; however, this is unlikely given the monthly pattern of MAE peer review in the VA Healthcare System. Fifth, the analysis did not consider patients who were not referred for angiography because of perceptions of unacceptable procedural risk. Finally, the possibility of residual confounding is inherent to the study's observational design. However, robust statistical methodologies were employed to limit these potential effects to the degree possible.

Conclusions

In this analysis of VA facilities that perform PCI, there was no deviation from routine PCI referral practices following an MAE. These findings argue against the presence of significant PCI risk aversion following MAEs across VA cardiac catheterization laboratories. Further research is needed to evaluate whether structured internal reporting mechanisms for MAEs, such as those employed by the VA Healthcare System, may be influential in mitigating PCI risk-aversion behaviors and can be reliably used to measure and report interventional quality.

Declaration of competing interest

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 U.S. Government. Dr. Waldo serves on the editorial board of *JSCAI*, has received grants from the National Institutes of Health and VA Health Services Research, and received investigator-initiated research support to the Denver Research Institute from Abiomed, Cardiovascular Systems Incorporated, and Janssen Pharmaceuticals. Dr. Valle has received unrelated consulting fees from Philips Medical, Janssen Pharmaceuticals, and Cardiovascular Systems Incorporated. Drs Kovach, Morrison, and Doll, and Ms Gunzburger reported no financial interests.

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Ethics statement and patient consent

This study was approved by the Colorado Multiple Institutions Review Board with a waiver of informed consent and adhered to all relevent ethical guidelines for clinical research.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2022.100460.

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