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The DISCO study—Does Interventionalists' Sex impact Coronary Outcomes?

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Abstract

Objectives: To examine the association of operator sex with appropriateness and outcomes of percutaneous coronary intervention (PCI).

Background: Recent studies suggest that physician sex may impact outcomes for specific patient cohorts. There are no data evaluating the impact of operator sex on PCI outcomes.

Methods: We studied the impact of operator sex on PCI outcome and appropriateness among all patients undergoing PCI between January 2010 and December 2017 at 48 non-federal hospitals in Michigan. We used logistic regression models to adjust for baseline risk among patients treated by male versus female operators in the primary analysis.

Results: During this time, 18 female interventionalists and 385 male interventionalists had performed at least one PCI. Female interventionalists performed 6362 (2.7%) of 239,420 cases. There were no differences in the odds of mortality (1.48% vs. 1.56%, adjusted OR [aOR] 1.138, 95% CI: 0.891–1.452), acute kidney injury (3.42% vs. 3.28%, aOR 1.027, 95% CI: 0.819–1.288), transfusion (2.59% vs. 2.85%, aOR 1.168, 95% CI: 0.980–1.390) or major bleeding (0.95% vs. 1.07%, aOR 1.083, 95% CI: 0.825–1.420) between patients treated by female versus male interventionalist. While the absolute differences were small, PCIs performed by female interventional cardiologists were more frequently rated as appropriate (86.64% vs. 84.45%, p-value <0.0001). Female interventional cardiologists more frequently prescribed guideline-directed medical therapy.

Conclusions: We found no significant differences in risk-adjusted in-hospital outcomes between PCIs performed by female versus male interventional cardiologists in

Abbreviations: AKI, acute kidney injury; AUC, appropriate use criteria; BMC 2, Blue Cross Blue Shield of Michigan Cardiovascular Consortium; OR, odds ratio; PCI, percutaneous coronary intervention.

Although Blue Cross Blue Shield of Michigan (BCBSM) and BMC2 work collaboratively, the opinions, beliefs and viewpoints expressed by the author do not necessarily reflect the opinions, beliefs and viewpoints of BCBSM or any of its employees.

Michigan. Female interventional cardiologists more frequently performed PCI rated as appropriate and had a higher likelihood of prescribing guideline-directed medical therapy.

KEYWORDS
appropriateness, gender, interventional, outcomes, sex

1 | INTRODUCTION

There is a large body of data demonstrating an association between patient gender and percutaneous coronary intervention (PCI) outcomes. For instance, women with acute coronary syndromes are less likely to be hospitalized[1] and are less likely to have reperfusion therapy and coronary angiography.[2,3] Female gender continues to be an independent predictor of in-hospital mortality after PCI for ST-elevation myocardial infarction (STEMI).[4-6] Although there is a large and growing body of research demonstrating the association between patient sex and outcomes after treatment for a number of medical conditions including acute myocardial infarction,[7] congestive heart failure,[8] and cancer,[9,10] there is a dearth of evidence evaluating the association between physician sex and patient outcomes.

Recently, Tsugawa et al. demonstrated that for patients with eight common medical conditions (including heart failure and arrhythmia) and across patients' severity, patients treated by female physicians had a lower mortality rate and lower readmissions at 30 days.[11] There has also been new data to suggest that physician-patient gender concordance (i.e., male physicians treating male patients and female physicians treating female patients) may play a role in outcomes.

Little is known about the association between the sex of the treating interventional cardiologist on PCI appropriateness and outcomes. Therefore, using the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) database, we compared clinical outcomes and appropriateness of PCI performed by female versus male interventional cardiologists at 48 hospitals in Michigan.

2 | METHODS

2.1 | Data sources and study population

We performed a retrospective analysis using data from the BMC2,[12] a quality improvement group that maintains a regional registry of all patients undergoing PCI in the state of Michigan. A more detailed description of the registry, including data collection and auditing practices, has been described previously.[13,14] Briefly, this is a prospective, multicenter, statewide registry of patients undergoing PCI at all non-federal hospitals in Michigan. Data is collected using the NCDR CathPCI data definitions[15] and is augmented by additional variables developed by BMC2. All data elements are prospectively defined, and a rigorous study coordinator training and education program is in place to ensure high data quality.

We included consecutive patients undergoing PCI at 48 hospitals between January 2010 and December 2017. PCI operator sex was determined using the Centers for Medicare and Medicaid Services (CMS) full replacement National Provider Identifier (NPI) file (NPPES downloadable file[16]) reflecting physicians in practice between May 23, 2005 through July 8, 2018. Seventeen out of the 48 hospitals were academic hospitals; academic hospitals were defined as hospitals that have an associated cardiology fellowship. Out of the 48 hospitals, six were classified as rural, 24 were classified as suburban and 18 were classified as urban.

2.2 | Study outcomes

The primary clinical outcomes included in-hospital mortality, post-procedural acute kidney injury, post-procedural blood transfusion, and post-procedural major bleeding. Mortality was defined as death from any cause prior to discharge following PCI.[15] Acute kidney injury was defined as ≥0.5 mg/dl absolute increase in creatinine. Major bleeding was defined as a hemoglobin drop of ≥5 g/dl.

For the risk-adjustment models, we estimated risks of mortality, AKI,[13,17] and transfusion[18] using BMC2 random forest risk models which incorporate baseline patient clinical and demographic characteristics.[19,20] Risk-adjusted mortality, AKI, and transfusion were estimated for sub-groups by the overall collaborative outcome incidence multiplied by the ratio of observed to expected outcome rates for the subgroup (overall rate * observed/expected ratio for each subgroup). Risk-adjusted rates of major bleeding were estimated using a logistical regression model including predicted risks for mortality, AKI, need for transfusion and patient gender as covariates. In addition, the primary outcomes were further stratified by the sex of the patient to assess physician-patient gender concordance.

We also used BMC2 clinical data to calculate appropriateness using the AUC developed by the American College of Cardiology. A score of 7–9 is considered appropriate, 4–6 may be appropriate and 1–3 is rarely appropriate.[21] An algorithm previously developed by members of the Clinical Outcomes and Assessment Program and the Northern New England Cardiovascular Disease Study Group was used to automate calculation of the AUC based on clinical data elements within the BMC2 database.[22,23] All of the unclassifiable cases were included in the denominator as part of all cases; only the cases falling in the top 3 appropriateness categories per the ACC guidelines were

reported in the numerator. Finally, we assessed discharge medications including anti-platelet therapy, statin, angiotensin-converting enzyme inhibitors, or angiotensin II receptor blockers and beta-blockers. For the assessment of discharge medications, we excluded patients who died prior to discharge, had contraindications to the specified medications, or were discharged to hospice or against medical advice.

2.3 | Statistical analysis

Pearson Chi-squared and Fisher's exact tests were used to compare categorical measures, and student T and Wilcoxon tests were used to compare continuous valued measures between patients treated by male and female operators. The absolute standardized difference (ASD)[24] was used to assess the magnitude and significance of the differences between male and female operators. A threshold of 10% was used for this purpose, with ASD greater than 10% used to identify baseline patient characteristics reflecting substantial imbalance. In contrast to statistical significance, ASD is not dependent upon sample size.[25,26] Thus, in the case of the very large samples often seen in registry data, ASD provides a better measure of meaningful baseline differences. We used linear regression models to assess the impact of operator and patient gender and operator by patient gender interactions on outcomes adjusting for estimated baseline risk.

In a sensitivity analysis, propensity matching was used to compare patients treated by male operators to patients treated by female operators. Five to one matching (between cases performed by male and female operators) without replacement was performed using a caliper of 0.25 SD of the propensity score and with exact matching required on patient gender. The variables for the propensity score model included age, weight, height, diabetes and treatment, chronic lung disease, chronic heart failure within 2 weeks prior to PCI, NYHA class within prior 2 weeks, PCI status (elective, urgent, emergent, salvage), PCI indication, CAD presentation, pre-PCI LVEF, pre-PCI hemoglobin, pre-PCI CK-MB, pre-PCI troponin, pre-PCI creatinine, angina class, cardiogenic shock, cardiac arrest, pre-PCI vasopressor use and history of atrial fibrillation. All analyses were performed using R version 3.4 software.

The authors are unable to share the raw data, due to contractual agreements between participating institutions and the BMC2 registry that prohibit data sharing with external agencies. However, the analysis code and metadata to support the study figures is available on request from Annmarie Forrest, Program Manager BMC2 (avassalo@med.umich.edu).

3 | RESULTS

Our study population consisted of 243,610 PCI procedures performed between January 2010 and December 2017 at 48 hospitals in Michigan. A total of 4188 patients were excluded due to incomplete/missing operator identification, inability to match NPI and missing operator sex, leaving 239,422 PCI procedures available for analysis (Figure S1). During this time, there were 18 female interventionalists and 385 male interventionalists who performed at least one PCI using unique operator NPIs. Female operators represented 4.5% of all operators and performed 6363 (2.66%) cases. Over the study period, female operators performed 2.5% to 3% of cases annually and performed a median of 340 cases (IQR 91–482) compared with a median of 508 cases (IQR 122–862) performed by male operators. Female operators were more likely to perform cases at hospitals associated with an ACGME accredited cardiology fellowship program (57.0% vs. 52.6%, $p < 0.001$).

Differences in baseline characteristics among patients who had a PCI performed by a male operator compared with a female operator are shown in Table 1. Compared with male interventional cardiologists, female interventional cardiologists performed PCI using radial access more frequently (37.4% vs. 26.4%, $p < 0.0001$). This was the only characteristic that exceeded the 10% ASD threshold for substantial imbalance. Female interventional cardiologists performed PCI on higher risk patients such as those presenting with STEMI, and patients with cardiogenic shock and were more likely to perform multi-vessel PCI. During the procedure, female interventional cardiologists had longer fluoroscopy times and higher fluoroscopy doses but used less contrast volume. Female interventionalists were more likely to perform multi-vessel PCI.

Results of the risk-adjusted analysis are summarized in the Figures 1–4. There were no significant differences between female and male interventional cardiologists in the risk-adjusted rates of mortality (1.48% vs. 1.56%, aOR 1.138, 95% CI: 0.891–1.452), acute kidney injury (3.42% vs. 3.28%, aOR 1.027, 95% CI: 0.819–1.288), transfusion (92.59% vs. 2.85%, aOR 1.168, 95% CI: 0.980–1.390) or major bleeding (0.95% vs. 1.07%, aOR 1.083, 95% CI: 0.825–1.420). There were no significant differences in the outcomes of male patients treated by male versus female interventional cardiologists or female patients treated by male versus female interventional cardiologists. Of the 6362 cases performed by female operators, 6303 (99.07%) were successfully matched in a five to one fashion in the propensity-matched analysis (Table S1). Similar findings were observed in propensity-matched analysis (Figure 5).

While the absolute differences were small, procedures performed by female operators were more likely to be rated as appropriate compared with male operators (86.64% vs. 84.45%, p value <0.0001) when assessed by appropriate use criteria (Table 2). Female interventional cardiologists tended to more frequently prescribe guideline-directed medical therapies like statins (97.13% vs. 94.67%, p value <0.0001) (Table 3).

4 | DISCUSSION

Our study has two principal findings. First, there were only 18 (4.5%) female interventional cardiologists practicing in the state of Michigan, and accordingly, the number of patients treated by them is small (2.66% of procedures). Secondly, there were no significant differences

TABLE 1 Baseline characteristics stratified by gender of operator

Characteristic	Male operator $N = 233{,}060$	Female operator $N = 6362$	*p* value	Abs. Std. diff
Demographics				
Age	65.32 ± 11.98	64.79 ± 11.85	$p < 0.001$	4.48
Male	155,814 (66.9%)	4155 (65.3%)	$p = 0.010$	3.27
White	200,688 (86.1%)	5350 (84.1%)	$p < 0.001$	5.67
History and risk factors				
Hypertension	199,145 (85.5%)	5364 (84.4%)	$p = 0.012$	3.13
Diabetes mellitus	90,708 (38.9%)	2532 (39.8%)	$p = 0.161$	1.78
Dyslipidemia	189,377 (81.3%)	5220 (82.2%)	$p = 0.062$	2.39
Cerebrovascular disease	36,281 (15.6%)	971 (15.3%)	$p = 0.508$	0.84
Peripheral arterial disease	36,708 (15.8%)	983 (15.5%)	$p = 0.522$	0.82
Chronic lung disease	44,699 (19.2%)	1104 (17.4%)	$p < 0.001$	4.72
Current/recent smoker (w/in 1 year)	66,779 (28.7%)	1778 (28.0%)	$p = 0.216$	1.58
Prior MI	81,676 (35.1%)	2258 (35.5%)	$p = 0.469$	0.92
Prior heart failure	40,506 (17.4%)	1089 (17.1%)	$p = 0.584$	0.7
Prior valve surgery/procedure	4307 (1.8%)	143 (2.2%)	$p = 0.020$	2.82
Prior PCI	106,867 (45.9%)	2741 (43.1%)	$p < 0.001$	5.58
CAD presentation				
No symptoms, no angina	10,980 (4.7%)	213 (3.3%)	$p < 0.001$	6.94
Symptoms unlikely ischemic	5817 (2.5%)	177 (2.8%)	$p = 0.150$	1.78
Stable angina	28,501 (12.2%)	747 (11.7%)	$p = 0.239$	1.51
Unstable angina	98,225 (42.2%)	2547 (40.0%)	$p < 0.001$	4.31
NSTEMI	52,193 (22.4%)	1511 (23.8%)	$p = 0.011$	3.21
STEMI or equivalent	37,290 (16.0%)	1167 (18.3%)	$p < 0.001$	6.21
Arterial access site				
Femoral	170,680 (73.2%)	3934 (61.9%)	$p < 0.001$	24.49
Radial	61,588 (26.4%)	2379 (37.4%)	$p < 0.001$	23.72
Other				
Pre-PCI LV ejection fraction	51.84 ± 12.92	52.56 ± 13.01	$p < 0.001$	5.49
Cardiogenic shock at start of PCI	4923 (2.1%)	186 (2.9%)	$p < 0.001$	5.17
CTO	8211 (3.5%)	208 (3.3%)	$p = 0.298$	1.40
Multi-vessel PCI	28,261 (12.4%)	900 (14.2%)	$p < 0.001$	5.60

Note: Values are mean ±SD or *n*/*N* (%).

Abbreviations: CAD, coronary artery disease; LV, left ventricle; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; NSTEMI, non ST-segment elevation myocardial infarction.

in in-hospital mortality, AKI, transfusion or major bleeding among patients treated by female versus male interventional cardiologists after adjusting for patient risk. Finally, PCIs performed by female interventional cardiologists were more frequently rated as appropriate and female interventional cardiologists more frequently prescribed guideline-medical therapy.

To our knowledge, this is the first study evaluating clinical outcomes based on the sex of the treating interventional cardiologist. This may be due to the fact that female interventional cardiologists continue to be markedly under-represented and only perform a small percentage of PCI cases.[27] While more than 50% of medical students and nearly 33% of practicing physicians are female, the percentage of females pursuing cardiology fellowship has remained stagnant between 21% and 23% since 2007.[28] In interventional cardiology, this number is even lower. Only 4.5% of interventional cardiologists are women and perform 3% of procedures based on National Cardiovascular Data Registry of PCIs.[27] It is important but not surprising that we found no significant differences in important clinical outcomes. Female interventionalists are more likely to use radial access. While there was no statistically significant difference in bleeding rates, there was a trend toward fewer transfusions in patients who had female operators ($p = 0.065$). Previous studies have raised the issue of

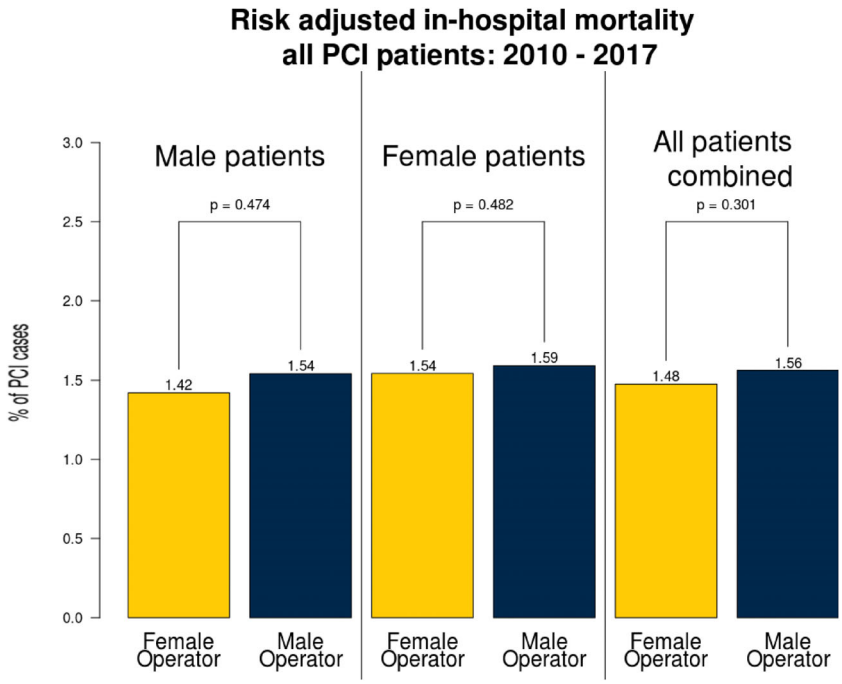

FIGURE 1 The risk adjusted in-hospital mortality of patients treated by female (maize bars) or male interventional cardiologists (blue bars) among male patients, female patients and overall population. Mortality was defined as death from any cause prior to discharge following PCI

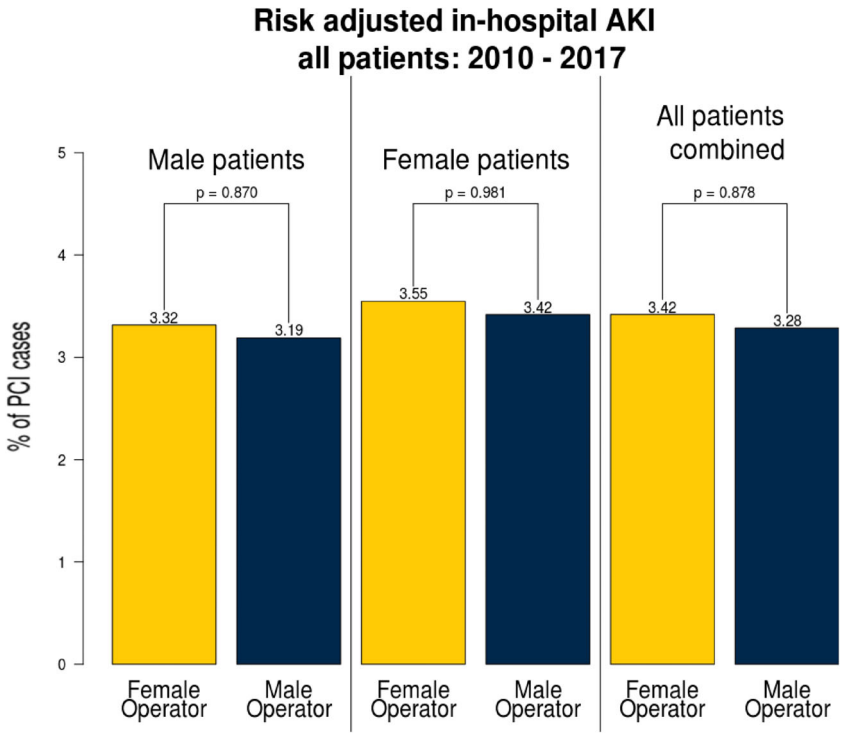

FIGURE 2 The risk-adjusted incidence of AKI (acute kidney injury) of patients treated by female (maize bars) or male interventional cardiologists (blue bars) among male patients, female patients and overall population. AKI was defined as > 0.5mg/d Lincrease in creatinine

gender concordance; Greenwood et al found that among female patients treated for acute myocardial infarction, those treated by female physicians had lower mortality.[29] We did not notice a similar signal in our study.

The Appropriate Use Criteria was developed by multiple organizations to provide a practical standard upon which to ensure the delivery of high-quality cardiovascular care.[21] It is generally accepted that appropriateness is an independent measure of healthcare value for PCI that needs to be considered separately when assessing the overall performance of the procedure,[22] While the absolute differences were small, procedures performed by female interventional cardiologists were more likely to be rated as appropriate. Female interventional cardiologists also prescribed more guideline-directed medical therapy. This is consistent with other previous studies showing that female physicians are more likely to follow guidelines based practice.[30-32] There have also been studies that showed the opposite—a study by

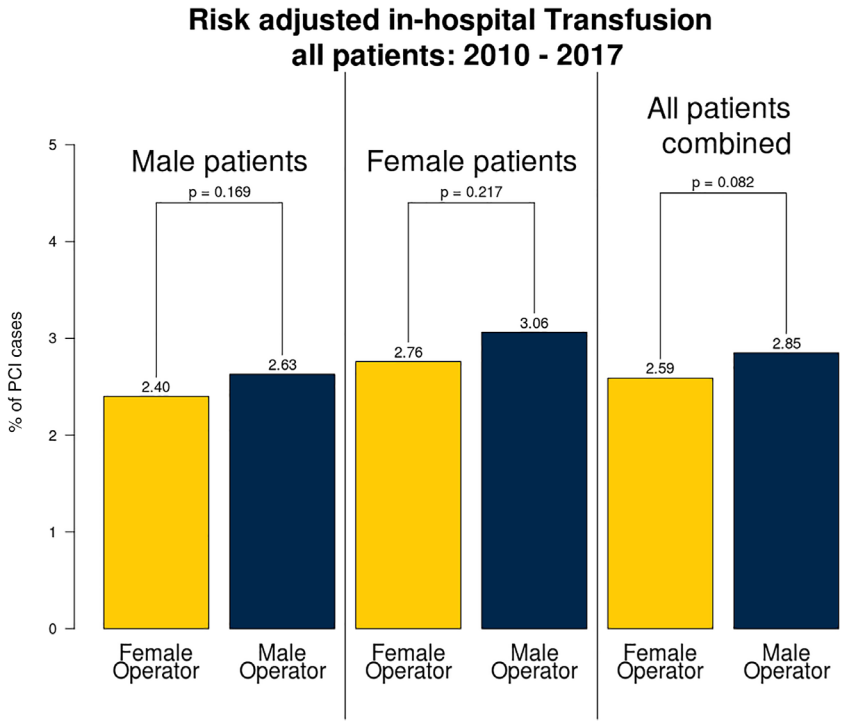

FIGURE 3 The risk adjusted in-hospital transfusions of patients treated by female (maize bars) or male interventional cardiologists (blue bars) among male patients, female patients and overall population

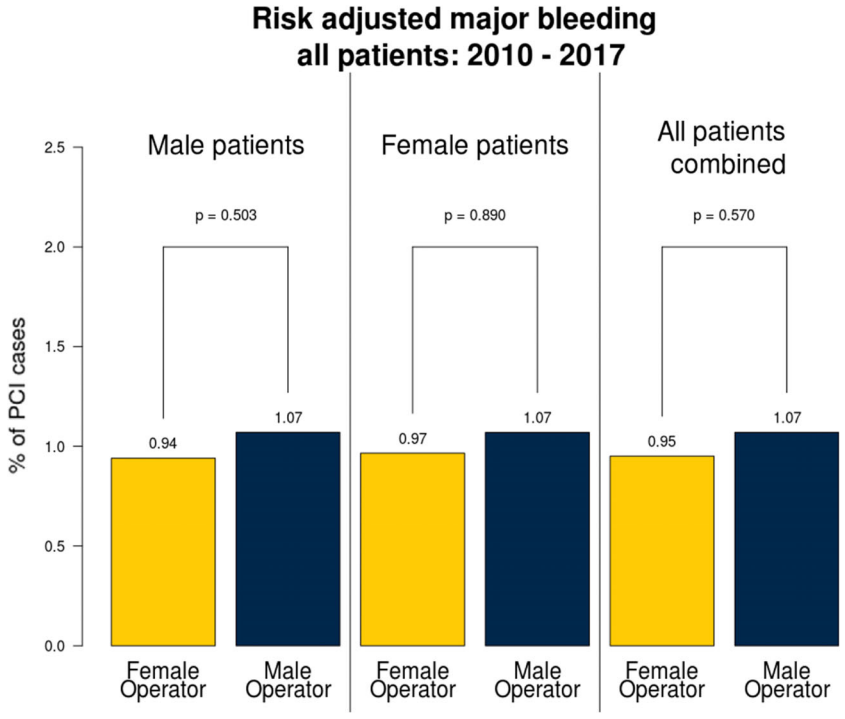

FIGURE 4 The risk adjusted in-hospital major bleeding of patients treated by female (maize bars) or male interventional cardiologists (blue bars) among male patients, female patients and overall population. Major bleeding was defined as a hemoglobin drop of >5g/dl

Gupta et al showed that male clinicians may have higher adherence to cardiovascular performance than female clinicians in the ambulatory cardiology setting.[33] However, in this study, the overall adherence to some performance measures was low for both male and female practitioners. The level of adherence for recommended therapy was higher in our study for both male and female practitioners. Although the team prescribing the medications at discharge may be different than the operator performing the procedure, the operator is part of the "care team" in helping assess which medications are necessary. Jones et al have shown that cooperation tended to increase with a rising proportion of females in the operating room[34]—similar cooperation may also contribute to better post PCI care in our study. Female interventionalists were also more likely to perform PCIs at hospitals with an ACGME accredited cardiology fellowship program; these academic

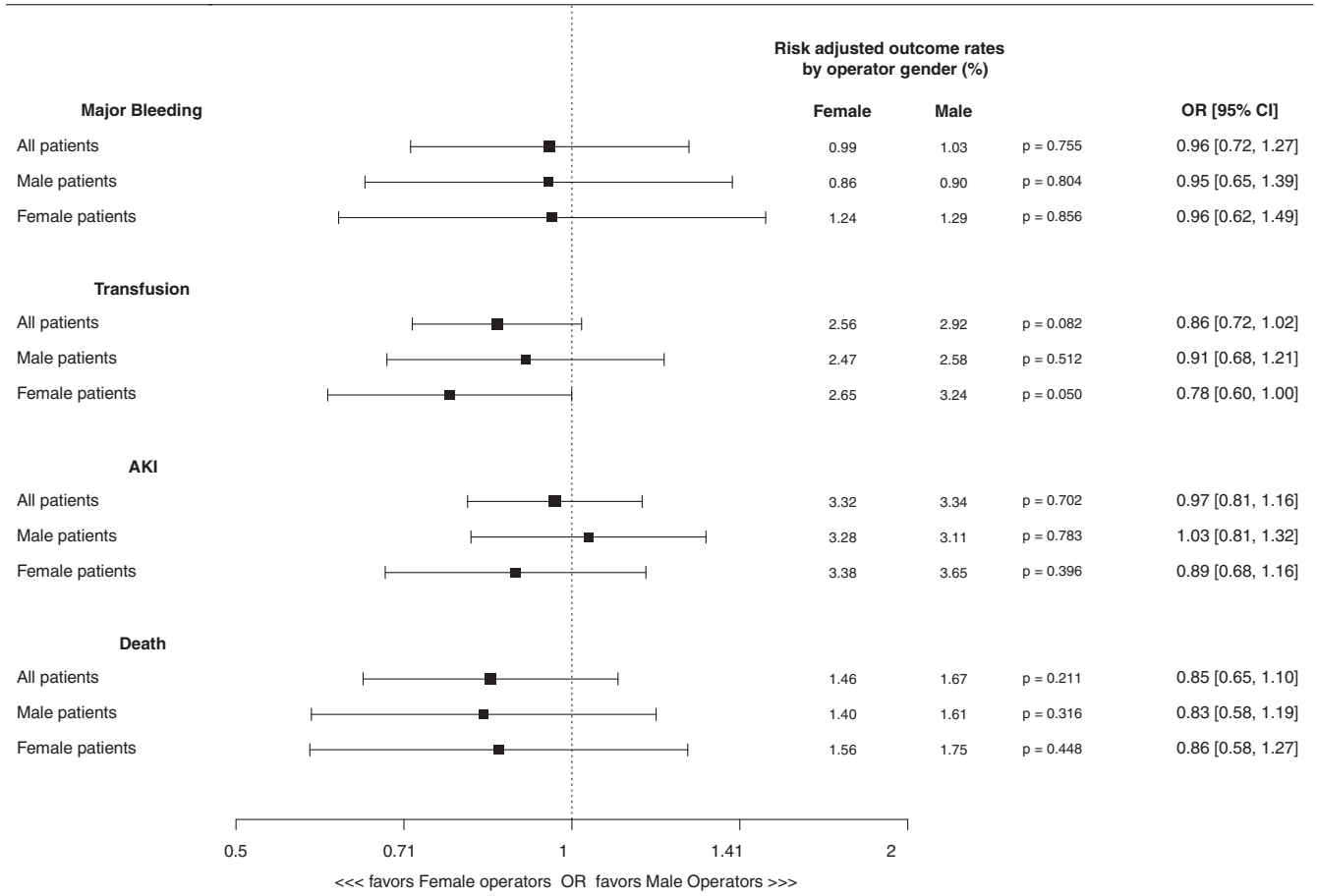

FIGURE 5 Odds of Study Outcomes using 5:1 Propensity Matching comparing female to male operators for all patients, and stratified by patient gender. Major bleeding was defined as hemoglobin drop of>5g/dl. Acute kidney injury was defined as ≥0.5 mg/dl absolute increase in creatinine

TABLE 2 Proportion of procedures rated as appropriate in female, male, and all patients by operator gender

	Female operator (%)	Male operator (%)	*p* value
Male patients	86.47	83.82	$p < 0.001$
Female patients	86.95	85.73	$p = 0.108$
Combined	86.64	84.45	$p < 0.001$

TABLE 3 Discharge medications stratified by sex of interventional cardiologist

	Female operator (%)	Male operator (%)	*p* value	Absolute std. difference (%)
Aspirin	99.16	98.66	0.0009	4.82
Clopidogrel	68.21	68.32	0.8599	0.23
Prasugrel or Ticagrelor	30.61	30.03	0.3295	1.26
Statin	97.13	94.67	<0.0001	12.42
ACE/ARB (LVEF <40)	86.79	86.50	0.8272	0.85
Beta-blocker (LVEF <40)	95.37	96.60	0.0654	6.29

hospitals may be more likely to have pharmacists and other support staff to aid in prescribing appropriate guideline-directed medical therapy.

Although there are many perceived barriers for females to enter the field of interventional cardiology including uncontrollable or unpredictable lifestyle, concern over long work hours and poor work/life balance,[35] these data suggest that females who are in this field provide excellent clinical care. While there were no significant differences in clinical outcomes, female interventional cardiologists tended to perform more appropriate PCI and more frequently prescribed guideline-directed medical therapy, both indicators of high-quality

care. Having more female interventionalists creates a more diverse workforce, which has been shown in other areas of business and in surgical operating rooms[34] to be beneficial. Diversity enriches the workplace by broadening employee perspectives, strengthening their teams and offering greater resources for problem resolution.[36]

The exceedingly small number of women in the field of interventional cardiology should serves as a wakeup call for our profession. There needs to be a focus on gender equity, and we need to develop strategies to encourage female trainees to pursue a career in interventional cardiology.

4.1 | Limitations

Our study should be interpreted in the context of important limitations. First, the BMC2-PCI registry is a regional database from the state of Michigan with an active focus on multicenter quality improvement and might or might not be representative of the wider population of patients undergoing PCI in the United States.[37] Our findings, however, reflect the work across the entire state of Michigan, and comprise the experience of both academic and community hospitals, which makes our findings more generalizable. Despite a rigorous analytical approach, our study if limited by the potential for selection bias due to unmeasured confounding inherent to observational studies.

5 | CONCLUSION

Female interventional cardiologists are scarce and perform a small percentage of PCI cases in Michigan. There was no significant difference in risk-adjusted outcomes of procedures performed by male versus female interventional cardiologists in Michigan. Female operators scored higher on appropriateness metrics and prescribed more guideline-directed medical therapy. Taken together, these findings underscore the importance of the cardiovascular community's focus[35] on developing strategies to encourage female trainees to pursue a career in interventional cardiology.

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CONFLICT OF INTEREST

Hitinder S. Gurm receives research support from Blue Cross and Blue Shield of Michigan, the National Institutes of Health Center for Accelerated Innovations, and Michigan Translational Research and Commercialization for Life Sciences Innovation Hub. He is the co-founder of, owns equity in, and is a consultant to Amplitude Vascular Systems. He also owns equity in Jiaxing Bossh Medical Technology Partnership and is a consultant for Osprey Medical. None of the authors have any conflicts directly relevant to this study.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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