Clinical Outcomes of Percutaneous Coronary Intervention in Patients Turned Down for Surgical Revascularization

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> Objectives: We examined clinical outcomes following percutaneous coronary intervention (PCI) in patients turned down for surgical revascularization across a broad population. Background: Prior studies suggest that surgical ineligibility is associated with increased mortality in patients with unprotected left main or multivessel coronary artery disease undergoing PCI. Methods: This study included consecutive patients who underwent PCI in a multicenter registry in Michigan from January 2010 to December 2014. Surgical ineligibility required documentation indicating that a cardiac surgeon deemed the patient ineligible for surgery. In-hospital outcomes included mortality (primary outcome), cardiogenic shock, cerebrovascular accident, contrast-induced nephropathy (CIN), and a new requirement for dialysis (NRD). Results: Of 99,370 patients at 33 hospitals with on-site surgical backup, 1,922 (1.9%) were surgically ineligible. The rate of ineligibility did not vary by hospital (range: 1.5-2.5%; P = 0.79). Overall, there were no major differences in baseline characteristics or outcomes between surgically ineligible patients and the rest (i.e., nonineligible patients): mortality (0.52% vs. 0.52%; P>0.5), cardiogenic shock (0.68% vs. 0.73%; P>0.5), cerebrovascular accident (0.05% vs. 0.19%; P=0.28), NRD (0.16% vs. 0.19%; P>0.5), CIN (2.7% vs. 2.3%; P = 0.27). Among 1,074 patients who underwent unprotected left main PCI, 20 (1.9%) were surgically ineligible and experienced increased rates of mortality (20.0% vs. 5.3%; P = 0.022; adjusted OR = 7.38; P < 0.001) and other complications as compared to the remainder. Conclusions: PCI in a broad population of surgically ineligible patients is generally safe. However, among patients who underwent unprotected left main PCI, those deemed surgically ineligible experienced significantly worse outcomes as compared to the rest. © 2016 Wiley Periodicals, Inc.

> Key words: percutaneous coronary intervention (PCI); coronary artery bypass grafting; health care outcomes; risk stratification; coronary artery disease

INTRODUCTION

The optimal method of revascularization for coronary artery disease (CAD), whether it is percutaneous coronary intervention (PCI) or coronary artery bypass

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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. grafting (CABG), has been a controversial and frequent topic of research for many years [1–12]. Physicians consider numerous factors when formulating their recommendation for revascularization, including, but not

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DOI: 10.1002/ccd.26781 Published online 21 September 2016 in Wiley Online Library (wileyonlinelibrary.com) limited to, the presence of diabetes mellitus, chronic kidney disease, systolic dysfunction, prior CABG, and the complexity of CAD [13–15]. In recent years, clinical guidelines and appropriate use criteria have been developed to assist physicians in making evidence-based recommendations [13,14,16].

Nevertheless, the decision to recommend surgical or percutaneous revascularization is complex, frequently requiring the input of general cardiologists, interventional cardiologists, and cardiac surgeons. Clinical guidelines advocate for a team-based, multidisciplinary, "Heart Team" approach to determining the optimal revascularization strategy for complex patients [13,14,16]. Through this multidisciplinary approach, patients may be deemed ineligible for a particular revascularization option.

Recent research has demonstrated that patients with unprotected left main or multivessel CAD who are deemed ineligible for surgical revascularization experience worse outcomes after PCI as compared to patients not deemed ineligible [17,18]. These studies reflect the experiences of PCI at tertiary care institutions. Historically, surgically ineligible patients referred for PCI are thought to represent a high-risk cohort. The characteristics and outcomes of PCI in patients turned down for surgical revascularization in broad community practice have not been studied. Therefore, using a large regional PCI database, we sought to describe the characteristics and outcomes of PCI in patients with documented surgical ineligibility within a diverse array of PCIcapable hospitals.

METHODS

We performed a retrospective analysis on data from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2), a regional registry of all patients undergoing PCI in Michigan. A more complete description of the registry, including data collection and auditing practices, has been described previously [19,20]. Briefly, this is a prospective, multicenter, statewide registry of patients undergoing PCI at any of the non-federal hospitals in Michigan. For the current study, consecutive patients undergoing PCI between January 2010 and December 2014 at the 33 hospitals with on-site cardiac surgery were included.

Patients that presented with ST-elevation myocardial infarction (STEMI) or pre-procedural cardiac arrest were excluded due to the emergent nature of treatment and a bias toward PCI in these individuals. Patients with a history of CABG were excluded, as the decision to recommend surgical or percutaneous revascularization often hinges on unique and important considerations such as repeat sternotomy, graft anatomy, and conduit availability. Finally, patients that underwent salvage PCI were excluded given the use of PCI as a last resort in these critically ill patients. Salvage PCI was defined as PCI in a patient who, within ten minutes prior to the start of the procedure, had received chest compressions or had been on unanticipated extracorporeal circulatory support [21]. Surgical ineligibility was defined as written documentation indicating that the patient was evaluated by a cardiac surgeon and felt not to be a surgical candidate for any reason. We did not collect information regarding the reason for surgical referral or for surgical ineligibility, as these reasons are often heterogeneous and poorly defined. We divided patients into two groups, those turned down for surgical revascularization and the remainder (who may or may not have been evaluated by a cardiac surgeon).

Outcomes and Subgroup Analysis

All outcomes were measured during the incident hospitalization when PCI was performed. The primary outcome measure was in-hospital mortality attributable to any cause. Secondary outcomes included the development of post-procedure cardiogenic shock, cerebrovascular accident (CVA), contrast-induced nephropathy (CIN), and a new requirement for dialysis (NRD). Post-procedure cardiogenic shock and CVA were defined as per the NCDR CathPCI registry definition [21]. CIN was defined as renal dysfunction resulting in a 0.5 mg dL⁻¹ absolute increase in a post-procedure creatinine measurement as compared to baseline. NRD was defined as any new, unplanned need for dialysis after PCI.

Clinical outcomes are reported for the overall cohort and by subgroups defined by percutaneously treated CAD anatomy. Diagnostic catheterization data were not routinely collected on all patients in the registry; therefore, we defined CAD anatomy by the site(s) of PCI per catheterization lab visit. Complex disease was defined as unprotected left main PCI, three-vessel PCI, or twovessel with proximal left anterior descending (LAD) PCI. Because of the exclusion of patients with prior CABG, all left main PCIs were considered unprotected. The hierarchy of categorization also followed the aforementioned sequence. For example, a patient who underwent left main and proximal LAD PCI would be classified as having left main disease, not two-vessel with proximal LAD disease. All other patients were categorized as having non-complex disease.

Statistical Analysis

Baseline characteristics and outcomes were compared between surgically ineligible patients and the

Catheterization and Cardiovascular Interventions DOI 10.1002/ccd. Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI). remainder using Pearson χ^2 or Fisher's exact test for categorical variables and Student *t* tests for continuous variables. Continuous variables were summarized using mean \pm SD. Outcome rates by surgical ineligibility were compared using Fisher's exact test. Pre-procedural risks of mortality, CIN, and need for transfusion were estimated using the BMC2 random forest prediction models (available for review at https://bmc2.org/calculators/multi). The methodology and specific implementations for CIN and transfusion endpoints have been validated and previously described elsewhere [22,23].

For the primary outcome of mortality, hierarchical logistic regression models were utilized incorporating patient baseline mortality risk and PCI-treated CAD anatomy as fixed effects and accounting for potential hospital level variability through the inclusion of a hospital random intercept. All analyses were performed using R version 3.2.1 [24]. Hierarchical generalized mixed effects regression models were fitted using the lme4 R package [25].

RESULTS

A total of 151,223 patients underwent PCI at the 33 participating centers between January 2010 and December 2014. Of these, 24,153 (16.0%) presented with STEMI, 2,893 (1.9%) experienced a pre-procedure cardiac arrest, 283 (0.2%) underwent salvage PCI, and 28,242 (18.7%) had a history of CABG. A total of 51,853 (34.3%) patients met at least one exclusion criteria, leaving 99,370 patients in the overall cohort. A total of 1,922 (1.9%) patients were turned down for surgery. The baseline characteristics of surgically ineligible patients and the remainder are presented in Table I. The two groups were largely similar in their baseline characteristics, with only prior myocardial infarction and prior PCI having occurred at a greater frequency in patients ineligible for surgery.

There was no significant site-level variation in the incidence of surgically ineligible patients across the 33 hospitals with on-site surgical backup (range: 1.5–2.5%; $X^2 = 25.5$ on 32 df; P > 0.5) (Fig. 1). In-hospital mortality was similar between the two groups (0.52% vs. 0.52%; P > 0.5; Fig. 2), and no significant difference was observed after adjusting for pre-procedural predicted risk of mortality, PCI-treated CAD anatomy, and hospital-level clustering in a hierarchical regression model (adjusted odds ratio [aOR] = 1.11; 95% confidence interval [CI] 0.57–2.15; P > 0.5). Furthermore, no significant differences were noted in secondary outcome measures (Fig. 2).

Stratification by PCI-treated CAD Anatomy

A total of 4,438 patients were defined as having complex disease, of which 81 patients (1.8%) had documentation of surgical ineligibility. The majority (95.8%; n/N = 1,841/1,922) of surgically ineligible patients had noncomplex disease (Table II). There was no difference in the distribution of PCI-treated CAD anatomy between patients turned down and not turned down for surgery (P > 0.5). Of note, no surgically ineligible patients underwent three-vessel PCI. No significant differences in primary or secondary outcomes were observed in any PCI-treated CAD anatomy subgroup other than left main PCI patients.

Among patients who underwent left main PCI (n = 1,074), those deemed surgically ineligible (n = 20) had significantly increased rates of in-hospital mortality (20.0% vs. 5.3%; P = 0.022), cardiogenic shock (25.0% vs. 5.1%; P = 0.004), and NRD (10.5% vs. 1.6%; P = 0.042) as compared to the remainder (n = 1,054; Fig. 3). Of note, 40% (n/N = 4/10) of inhospital deaths in all surgically ineligible patients occurred in those who underwent left main PCI.

The effect of surgical ineligibility on mortality varied significantly between patients with left main PCI compared to those with other PCI-treated CAD anatomy after adjusting for predicted pre-procedural mortality risk, CAD anatomy, and hospital-level clustering (likelihood ratio test for left main PCI by ineligibility interaction: LRT = 12.7 on 1 df, P < 0.0001). In stratified, adjusted hierarchical regression analysis, again adjusting for predicted baseline risk and hospital level clustering fit within the left main PCI subgroup, mortality was strongly associated with surgical ineligibility (aOR = 7.38, 95% CI 2.32–23.49, P < 0.001).

DISCUSSION

Recent research has demonstrated that surgical ineligibility is associated with inferior outcomes after PCI in patients with complex CAD [17,18]. Our study significantly adds to this body of literature through three major findings. First, it appears that broadly, PCI in patients deemed ineligible for surgical revascularization is safe, given that there is no significant difference in multiple, clinically relevant, in-hospital outcomes including death. Second, as noted in prior studies, individuals who were deemed ineligible for surgery and underwent left main PCI suffered significantly worse outcomes as compared to the rest of the cohort, highlighting the potential additive effect of surgical ineligibility in high-risk, complex CAD [17,18]. Third, there was no significant variation in the frequency of

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TABLE I. Bas	eline Characteristics of	of Surgically	Ineligible	Patients	and Others
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	Surgically ineligible	Others	
Variable	(<i>n</i> = 1,922)	(<i>n</i> = 97,448)	P value
Age (years)	64.5 ± 11.8	64.8 ± 11.9	0.30
Male	63.5%	63.8%	0.80
Body mass index (kg m^{-2})	30.9 ± 7.8	30.8 ± 7.4	0.69
Current/recent smoker	30.4%	28.5%	0.08
Hypertension	87.0%	86.8%	0.81
Dyslipidemia	84.9%	83.9%	0.20
Diabetes mellitus	37.8%	37.9%	0.97
Cerebrovascular disease	14.3%	14.2%	0.92
Peripheral arterial disease	15.9%	14.6%	0.12
Prior myocardial infarction	35.2%	32.1%	0.004
Prior heart failure	15.7%	14.8%	0.27
Prior valve surgery	1.1%	0.9%	0.40
Prior PCI	48.0%	45.6%	0.04
End-stage renal disease	2.5%	2.4%	0.84
Chronic lung disease	19.1%	19.3%	0.80
History of atrial fibrillation	10.9%	11.0%	0.83
Current/recent gastrointestinal bleeding	0.7%	1.0%	0.25
Left ventricular ejection fraction	$53.6\% \pm 12.0\%$	$53.4\% \pm 12.1\%$	0.56
Baseline creatinine (mg dL $^{-1}$)	1.16 ± 1.06	1.14 ± 0.99	0.42
Baseline GFR $(mL/min/1.73 m^2)^a$	74.97 ± 24.30	75.46 ± 24.38	0.39
Baseline hemoglobin (g dL^{-1})	13.42 ± 1.80	13.38 ± 1.86	0.24
Stable angina presentation	17.1%	16.5%	0.48
Unstable angina presentation	49.0%	48.3%	0.55
NSTEMI presentation	24.3%	25.4%	0.28
Cardiogenic shock ^b	1.0%	0.8%	0.20
IABP	0.7%	0.8%	0.57
Non-IABP mechanical ventricular support	0.8%	0.6%	0.42
Chronic total occlusion treated	3.5%	3.0%	0.20
Bifurcation lesion treated	9.5%	9.2%	0.63
Pre-procedural predicted mortality risk ^c	$0.57\% \pm 2.28\%$	$0.59\% \pm 2.32\%$	0.69
≥ 1 "high-risk" PCI-treated lesion ^d	55.2%	54.6%	0.63
Emergent PCI	2.3%	2.1%	0.50

All percentages represent frequencies, except for left ventricular ejection fraction and pre-procedural predicted mortality risk, which are presented as mean \pm standard deviation. Where nominal values are used, they are presented as mean \pm standard deviation.

GFR = glomerular filtration rate; IABP = intra-aortic balloon pump; NSTEMI = Non ST-elevation myocardial infarction; PCI = percutaneous coronary intervention.

^aThe Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation was used [26].

^bRepresents the frequency of patients in cardiogenic shock within 24 h prior to the procedure or at the start of the procedure.

^cThe pre-procedural risk of mortality was estimated using the BMC2 random forest prediction model available for review at https://bmc2.org/calculators/multi.

^dLesion characteristics consistent with a "C lesion" as defined by the NCDR CathPCI Registry [21].

PCI in surgically ineligible patients amongst a diverse group of PCI-capable hospitals within this region.

Though PCI in patients with documented surgical ineligibility appears to be safe, these findings must be interpreted with certain caveats. One potential reason why PCI appears safe in this population may be because these surgically ineligible patients were inherently deemed eligible for PCI by the interventional cardiologist performing the procedure. Undoubtedly, there are patients who are deemed ineligible for surgery and PCI, thereby never undergoing revascularization. The outcomes of these patients were not collected or reported. When assessing the outcomes of PCI by PCI-treated CAD anatomy, we attempted to classify patients according to the severity of their disease by using the appropriate use criteria for multivessel disease as a guide [16]. Patients who underwent two-vessel with proximal LAD PCI experienced similar outcomes when stratified by surgical ineligibility. There is a possibility that this finding is due to misclassification of CAD complexity, given that we classified CAD anatomy based on lesions treated by PCI and not native CAD at the time of diagnostic catheterization. Therefore, patients with multivessel complex CAD who underwent staged PCI may have been categorized as having

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Fig. 1. The percentage of percutaneous coronary interventions performed in surgically ineligible patients by hospital— The bar graph represents the percent of PCI cases performed in surgically ineligible patients in each hospital participating in the BMC2 registry. The sites are ordered from the lowest to the highest frequency site. PCI = percutaneous coronary intervention. [Color figure can be viewed at wileyonlinelibrary.com.]



Fig. 2. In-hospital outcome rates in all patients—Bar graphs of primary and secondary in-hospital outcomes in all patients stratified by ineligibility for surgery. The specific outcome rate is noted above each bar. [Color figure can be viewed at wileyonlinelibrary.com.]

non-complex disease. Additionally, some patients with multivessel native CAD would have been categorized as having noncomplex disease if they underwent PCI of select lesions (i.e., incomplete revascularization), if the interventional cardiologist felt that this would provide the optimal risk/benefit ratio. Nevertheless, the generally favorable outcomes in the overall population are reassuring.

Though only 20 surgically ineligible patients underwent left main PCI, 4 (20%) died during the hospitali-Catheterization and Cardiovascular Interventions DOI 10.1002/ccd.

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TABLE II. Distribution of Percutaneously Treated Coronary Artery Disease Anatomy Stratified by Surgical Ineligibility

	Surgically ineligible	Others
Percutaneously treated	e	
CAD anatomy	(n = 1,922)	(n = 97,448)
Complex disease	81	4,357
	(4.2%)	(4.5%)
Left main disease	20	1,054
	(1.0%)	(1.1%)
Three-vessel disease	0	37
	(0.0%)	(0.0%)
Two-vessel with proximal	61	3,266
LAD disease	(3.2%)	(3.4%)
Non-complex disease	1,841	93,091
<u>^</u>	(95.8%)	(95.5%)

Values are n (%).

PCI=percutaneous coronary intervention; CAD=coronary artery disease; LAD=left anterior descending artery.



Fig. 3. In-hospital outcome rates in the left main PCI subgroup—Bar graphs of primary and secondary in-hospital outcomes in patients who underwent left main PCI stratified by ineligibility for surgery. The specific outcome rate is noted above each bar. PCI = percutaneous coronary intervention. [Color figure can be viewed at wileyonlinelibrary.com.]

zation. This surgically ineligible subgroup also had increased rates of cardiogenic shock and NRD. Even after adjustment, surgical ineligibility was associated with a sevenfold increase in in-hospital mortality in this subgroup. Although the absolute number of patients in this subgroup is small, this finding is consistent with prior studies assessing the relationship between surgical ineligibility and PCI outcomes [17,18]. Future studies should attempt to elucidate the specific, and often complex, reasons for surgical ineligibility that may confer this increased risk. It is also noteworthy that a substantially larger number of patients underwent left main PCI without being turned down for surgery and the general outcome in this cohort was excellent. Although the total number of patients who were referred to surgery for left main disease is not available, it is likely that these 20 patients represent a highly selected and unique subset of patients who were at a high risk of adverse outcomes from either revascularization strategy.

Multiple studies have demonstrated significant hospital-level variation for a number of important cardiovascular outcomes [27–29]. The 33 nonfederal PCIcapable hospitals in our statewide registry vary from community hospitals to quaternary teaching hospitals. We found no significant difference in the rate of PCI in surgically ineligible patients across these hospitals. This suggests that practice patterns are broadly similar across the state. Notably, both interventional cardiologists and cardiac surgeons participate in statewide collaborative quality improvement initiatives and such practice uniformity may or may not exist across geographic regions that do not participate in such initiatives [30].

Clinical guidelines advocate for the use of a multidisciplinary Heart Team approach when evaluating revascularization options for patients with complex CAD [13,14,16]. Therefore, it is surprising that the vast majority of surgically ineligible patients (95.8%) had noncomplex disease. As stated above, this number may be an overestimate due to our classification scheme. Nevertheless, even if we were to assume a substantial proportion of misclassification, the majority of patients would still likely have noncomplex disease. It is unclear why these patients were referred for surgery, let alone deemed ineligible. It is possible that these patients may have had more diffuse and complex coronary lesions or other cardiac conditions such as severe valve disease that may have led to surgical referral. In the future, the number of patients with complex CAD evaluated for surgical and percutaneous revascularization options will likely increase as the utilization of a Heart Team approach grows [31-33]. We suspect that documentation of these collaborative decisions will provide a better understanding of referral practices between cardiologists and cardiac surgeons and allow for more rigorous research into the effects of surgical ineligibility on patient outcomes.

Fortunately, through the emergence of new healthcare information technologies and the mandate for the meaningful use of electronic health records, "big data" analytics may be able to help us better understand these issues in the future. For example, the application of natural language processing systems to electronic medical records have already resulted in improved prediction and detection of outcomes, and is being used to develop clinical registries [34–36]. We imagine that the application of these technologies to the vast wealth of clinical information in electronic health records will ultimately allow us to obtain a more complete and nuanced understanding of complex clinical decisions such as the reasons for surgical referral and the rationale for surgical ineligibility (or eligibility) in patients with CAD.

There are several limitations in our study that deserve specific mention. First, as noted above, we may have potentially misclassified the complexity of CAD due to inherent limitations in the accurate collection of native CAD anatomy, requiring us to use percutaneously treated CAD anatomy. Second, the registry follows a rigorous definition for surgical ineligibility, and surgical ineligibility cannot be assigned by a cardiologist or following a "curbside" consult. We had no method of accounting for non-documented surgical ineligibility, but our rigorous definition would increase the specificity of our findings. Furthermore, as noted by Gasparovic *et al.*, we believe that in order to accurately study the association between surgical ineligibility and PCI outcomes, cardiac surgeons, not surrogate decisionmakers, should determine a patient's eligibility for surgery [37]. Third, we do not have data on intermediateand long-term outcomes. As demonstrated previously, there may be a more substantial difference in outcomes between these two groups in the long-term [17,18]. Fourth, despite collecting PCI information from multiple centers over a 4-year time period, our statistical power to detect significant differences in outcomes was limited by the small number of patients deemed surgically ineligible. This limitation underscores the need for ongoing research studying the impact of surgical ineligibility on PCI outcomes, and the consideration of including this variable in large, national PCI registries.

CONCLUSIONS

PCI in a broad population of surgically ineligible patients appears safe, potentially highlighting the discretion utilized by interventional cardiologists in selecting these patients. Importantly though, there is a substantial effect of surgical ineligibility on mortality in the subgroup of patients who underwent unprotected left main PCI, although this finding should be interpreted with caution as only 20 surgically ineligible patients underwent left main PCI. Our findings may assist physicians and patients in more accurately estimating the risks associated with PCI in patients with documented surgical ineligibility.

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Blue Cross Blue Shield of Michigan Cardiovascular Consortium registry.

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