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## Surgical Ineligibility and Mortality Among Patients with Unprotected Left Main or Multivessel Coronary Artery Disease Undergoing Percutaneous Coronary Intervention

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### Abstract

**Background**—Decisions to proceed with surgical versus percutaneous revascularization for multivessel coronary artery disease are often based on subtle clinical information that may not be captured in contemporary registries. The present study sought to evaluate the association between surgical ineligibility documented in the medical record and long-term mortality among patients with unprotected left main or multivessel coronary artery disease undergoing percutaneous coronary intervention (PCI).

**Methods and Results**—All subjects undergoing non-emergent PCI for unprotected left main or multivessel coronary artery disease were identified at two academic medical centers from 2009 – 2012. Documentation of surgical ineligibility was assessed through review of the electronic medical record. Cox proportional hazard models adjusted for known mortality risk factors were created to assess long-term mortality in patients with and without documentation of surgical ineligibility. Among 1013 subjects with multivessel coronary artery disease, 218 (22 %) were deemed ineligible for coronary artery bypass graft surgery. The most common explicitly cited reasons for surgical ineligibility in the medical record were poor surgical targets (24 %), advanced age (16 %) and renal insufficiency (16 %). After adjustment for known risk factors, documentation of surgical ineligibility remained independently associated with an increased risk of in-hospital (OR: 6.26, 95% CI: 2.16 – 18.15, P<0.001) and long-term mortality (HR: 2.98, 95% CI: 1.88 – 4.72, P<0.001) after PCI.

**Conclusions**—Documented surgical ineligibility is common and associated with significantly increased long-term mortality among patients undergoing PCI with unprotected left main or

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multivessel coronary disease, even after adjustment for known risk factors for adverse events during percutaneous revascularization.

## Keywords

Percutaneous coronary intervention; risk-adjustment; surgical eligibility

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## Background

The optimal revascularization strategy for patients with left main or multivessel coronary artery disease has been an important focus for comparative effectiveness research.<sup>1-5</sup> Several cohort studies and meta-analyses have suggested that coronary artery bypass graft surgery (CABG) is associated with reduced adverse events when compared to percutaneous coronary intervention (PCI) for revascularization of these patients.<sup>1,3,6,7</sup> Additional randomized trials have confirmed that diabetic patients with this coronary anatomy may particularly benefit from surgical revascularization, though outcomes among non-diabetic patients are similar.<sup>5,8</sup> With this in mind, clinical guidelines and appropriate use criteria have favored surgical revascularization among patients with left main or multivessel coronary artery disease when there are no other extenuating circumstances.<sup>9-11</sup> In clinical practice, however, physicians commonly encounter patients that would have been excluded from clinical trials due to significant medical comorbidities and thus may not be subject to their findings.

The most compelling reason clinicians may choose one revascularization strategy over another occurs when a patient is deemed eligible for only one of the potential options.<sup>12</sup> The determination of eligibility for surgical revascularization is inherently subjective and may be due to factors such as the perceived frailty of the patient or the quality of the distal arteries to accept bypass grafts. Several of these characteristics are not measured or too subtle to be captured in procedural registries and thus not incorporated into commonly used risk models for percutaneous revascularization.<sup>12</sup> Because of this, these risk models may inadequately characterize procedural risk in several situations where they are commonly employed: 1) comparative effectiveness research, 2) assessment of hospital quality<sup>13</sup> and 3) clinical decision making.<sup>14</sup> Previous examination of the prevalence and impact of documented ineligibility for surgical revascularization has been limited to a single study of patients with unprotected left main disease.<sup>12</sup> There are limited data examining surgical ineligibility among the broader population of patients with “surgical anatomy,” including patients with multivessel coronary artery disease.

With this in mind, the present study sought to 1) examine the frequency of documented surgical ineligibility among patients with known unprotected left main or multivessel coronary artery disease undergoing PCI and 2) assess the association between surgical ineligibility and mortality after adjustment for risk factors routinely used to predict mortality in clinical registries for PCI.

## Methods

### Population

All patients presenting to two academic medical centers within an integrated health system (Brigham and Women's Hospital and Massachusetts General Hospital) that undergo percutaneous or surgical coronary revascularization are included in an ongoing institutionally sponsored registry, the Partners Long-Term Outcomes Database. This registry includes data fields for the National Cardiovascular Data Registry (NCDR) CathPCI registry as well as the Society of Thoracic Surgeons (STS) dataset and relies on linkage to the National Death Index to assess long-term mortality using direct identifiers. The present project focused on patients with coronary anatomy suitable for surgical revascularization that subsequently underwent PCI. Surgical anatomy was defined as one of the following: 1) unprotected left main coronary artery disease (>50 %), 2) three vessel coronary artery disease (>70 %) or 3) two vessel coronary artery disease with stenosis (>70 %) in the proximal left anterior descending artery as defined in the appropriate use criteria for PCI.<sup>9,11</sup> To ensure that only non-emergent cases were included, subjects that underwent emergent revascularization for cardiac arrest, cardiogenic shock or ST-elevation myocardial infarction were excluded from the analysis. Patients with a history of prior CABG were also excluded as they represent a subgroup of patients for whom the underlying coronary anatomy and risks of repeat surgical revascularization are unique. The present project has been reviewed and approved with a waiver of informed consent from the institutional review board at Partners Healthcare.

### Measurements

Clinical and procedural information was abstracted from the electronic medical record and included in the institutional registry. The entire electronic medical record, including admission notes, consult notes, nursing notes, outpatient notes, catheterization reports and discharge summaries, was then queried to identify the presence of a cardiothoracic surgery consult note or explicit documentation of surgical ineligibility at any time prior to percutaneous revascularization. Surgical ineligibility was defined by the treating clinicians using terms such as "ineligible for surgery" or "too high risk for surgery" and independent of the views of the physician chart abstractors. Because of this, subjects that did not have clear and explicit documentation of surgical ineligibility were considered eligible for bypass surgery. Similarly, subjects with a documented patient preference for percutaneous revascularization were also deemed eligible for surgery and noted to have explicit documentation of a discussion regarding treatment options. For those that were deemed ineligible, the explicitly documented reasons for surgical ineligibility in the medical record were recorded and further categorized according to a previously published taxonomy.<sup>12</sup> To assess interobserver variability, two independent blinded physicians reviewed the electronic medical record for a random 10 % of the cohort and the results were compared. Long-term mortality was assessed through a review of the National Death Index and subsequent linkage with the institutional registry, as described previously.<sup>15</sup>

## Statistical Analysis

Summary statistics were reported as means with standard deviations (SD) for continuous variables or medians and interquartile ranges (IQR) for non-normally distributed continuous data. T-tests and Mann-Whitney U tests were used to compare normally and non-normally distributed continuous variables respectively. Chi-squared tests were used to evaluate differences in proportions. Interobserver variability was assessed with the Kappa statistic. Kaplan-Meier survival curves were generated stratified by the presence or absence of surgical ineligibility documentation and log-rank tests were used to compare the curves. Using a previously validated model for procedural risk from the NCDR CathPCI dataset, logistical regression models were created with and without the addition of documented surgical ineligibility as a covariate to assess in-hospital mortality.<sup>14,16</sup> Similar cox proportional hazards models with and without documentation of surgical ineligibility were also created to assess long-term mortality. The variables incorporated into both of these models included demographic characteristics (age, body mass index), past medical history (cerebrovascular disease, heart failure, peripheral vascular disease, diabetes mellitus, renal disease requiring hemodialysis, prior PCI), cardiac function (ejection fraction), presentation (cardiogenic shock, ST-elevation myocardial infarction) and angiographic characteristics (in-stent thrombosis, chronic total occlusion, disease in the left main coronary artery, disease in the proximal left anterior descending coronary artery, multivessel coronary artery disease).<sup>14,16</sup> These models were then used to calculate predicted in-hospital and long-term mortality, respectively. To quantify the extent to which surgical ineligibility improved mortality prediction over the NCDR risk score, we calculated the adjusted hazard ratio and integrated discrimination index (IDI) for surgical ineligibility as described previously.<sup>17</sup> C-statistics were also computed for the model with and without the addition of surgical ineligibility as a covariate. These c-statistics were subsequently compared using the method of DeLong, the standard method to compare correlated or nested c-statistics.<sup>18</sup> All statistical analyses were performed using SAS 9.3 (Cary, NC). A p-value < 0.05 was considered statistically significant.

## Results

### Population

Among 6960 subjects undergoing non-emergent PCI from 2009 – 2012, 1013 (15 %) had unprotected left main or multivessel coronary artery disease. Using all available documents in the electronic medical record, 218 (22 %) subjects were deemed ineligible for surgical revascularization by the treating clinicians (Figure 1). The interobserver agreement of assessing documentation of surgical ineligibility within the electronic medical record was high (K: 0.923, 95% CI: 0.837 – 1.000).

### Demographics

The demographic characteristics for those with documentation of surgical ineligibility and those without are reproduced in Table 1. Ineligible subjects were older (72 vs. 67 years,  $P < 0.001$ ) and more likely to be female (42 % vs. 66 %,  $P = 0.039$ ). A greater proportion of patients deemed ineligible for surgery had concomitant cerebrovascular disease (27 % vs. 13 %,  $P < 0.001$ ), chronic lung disease (30 % vs. 14 %,  $P < 0.001$ ), congestive heart failure (38 %

vs. 12 %,  $P<0.001$ ), diabetes mellitus (45 % vs. 38 %,  $P=0.039$ ), hypertension (92 % vs. 86 %,  $P=0.015$ ), peripheral artery disease (36 % vs. 15 %,  $P<0.001$ ) and a prior myocardial infarction (52 % vs. 31 %,  $P<0.001$ ). The predicted in-hospital mortality for those that were surgically ineligible was also increased (0.023 vs. 0.009,  $P<0.01$ ).

### Angiography

The angiographic characteristics for those with and without documentation of surgical ineligibility are shown in Table 2. Subjects ineligible for surgical revascularization were more likely to undergo procedures through the femoral approach (81 % vs. 63 %,  $P<0.001$ ). A larger proportion of patients deemed ineligible for surgery had left main disease (33 % vs. 10 %,  $P<0.001$ ) and had high complexity lesions (51 % vs. 34 %,  $P<0.001$ ). The number of lesions ( $P<0.001$ ), stents placed ( $P<0.001$ ) and length of stents ( $P<0.001$ ) were all significantly greater among surgically ineligible patients undergoing percutaneous revascularization as well. Subjects that were deemed eligible for surgical revascularization, however, had a greater number of vessels revascularized ( $P<0.001$ ).

### Ineligibility

The sources of documentation for surgical ineligibility are included in Table 3. As shown, a documented evaluation by the cardiothoracic surgery service was present in 95 (9%) of the 1013 patients undergoing percutaneous revascularization with surgical anatomy. In the 218 patients deemed ineligible, formal surgical evaluation and documentation was identified in 63 (29%) of the 218 patients. For those deemed ineligible for surgery, the majority of documentation addressing surgical candidacy was obtained from a cardiology consult note (37 %), the discharge summary (24 %) or the cardiac catheterization report (21 %) detailing the revascularization procedure. The majority of patients considered eligible for surgery did not have explicit documentation discussing surgical candidacy in the electronic medical record (81 %). As shown in Table 4, poor surgical targets (24 %), advanced age (16 %) and renal insufficiency (16 %) were the most commonly cited characteristics that were deemed to significantly increase the surgical risk.

### Mortality

The unadjusted in-hospital mortality among patients undergoing percutaneous revascularization was greater for those deemed ineligible for cardiac surgery (15 / 218, 7 %) compared to those that were eligible for the procedure (5 / 793, 1 %,  $P<0.001$ ). Unadjusted long-term mortality was also significantly greater in subjects deemed ineligible for surgery compared with those that were considered surgical candidates, as shown in Figure 2 (HR: 4.81, 95% CI: 3.12 – 7.40). After adjustment for predicted mortality risk, surgical ineligibility remained independently associated with increased odds of in-hospital death (OR: 6.26, 95% CI: 2.16 – 18.15,  $P<0.001$ ) and long-term mortality (HR: 2.98, 95 % CI: 1.88 – 4.72,  $P<0.001$ ). The addition of surgical ineligibility to the previously validated risk-adjustment model significantly improved the predictive capability of the model (c-statistic 0.753 of NCDR risk score vs. 0.792 including surgical ineligibility variable,  $P<0.01$ ). The integrated discrimination improvement after the addition of surgical ineligibility to the model was 0.04 (95% CI: 0.02 – 0.05) and the relative integrated discrimination

improvement was 0.40 (95% CI: 0.21 – 0.60), suggesting marked improvement in risk discrimination with addition of surgical ineligibility to the risk model.

## Discussion

The present study evaluated over 1000 consecutive patients with left main or multivessel coronary artery disease undergoing percutaneous revascularization in an integrated health system. Within this population, we found that documented surgical ineligibility was common and associated with significantly greater in-hospital and long-term mortality even after accounting for risk factors employed in a contemporary and widely used risk adjustment model for percutaneous revascularization. In fact, the addition of surgical ineligibility as a covariate to this model significantly improved its ability to predict mortality. These findings have important implications for comparative effectiveness research, evaluating hospital quality and procedural appropriateness, and the application of risk-prediction estimates to guide clinical decision making.

### Comparative Effectiveness Research

The optimal revascularization strategy for patients with multivessel coronary artery disease has long been a subject of interest in comparative effectiveness research. Over the last three decades, numerous randomized trials have been performed to evaluate clinical outcomes among those treated with surgical or percutaneous revascularization.<sup>5,8</sup> Observational data, however, has not always remained consistent with these findings.<sup>19,20</sup> Previous research has demonstrated that surgical ineligibility, a characteristic often not measured in contemporary observational datasets, was associated with a 5 – 6 fold increase in mortality among 101 patients undergoing unprotected left main PCI.<sup>12</sup> Our results expand upon these findings by including all patients with coronary anatomy that would favor surgical revascularization according to current professional society guidelines and appropriate use criteria – those with three vessel coronary artery disease or two vessel disease with a severe stenosis in the proximal left anterior descending artery. The data demonstrate that documentation of surgical ineligibility confers additional risk in these populations as well, even after adjusting for contemporary risk factors. It is possible that surgical ineligibility in itself may represent a variety of other clinical characteristics that are poorly captured in administrative or clinical datasets, including general frailty or poor psychosocial support. Due to both their high prevalence and large effect size, these unmeasured characteristics have the potential to undermine the results of large observational studies comparing revascularization strategies, even those employing rigorous statistical methods to limit confounding.<sup>21</sup>

### Hospital Quality Assessment and Appropriateness

Risk-adjusted mortality is a commonly employed benchmark to assess hospital PCI quality. The accuracy of such reports hinges, in part, on the inclusion of prognostically important variables in risk-adjustment models as well as their distribution among hospitals.<sup>22</sup> In Massachusetts, where these data are used to publicly profile hospital performance, the importance of documenting PCI cases done for “compassionate use” was found to significantly improve mortality risk-prediction and attenuate the decline in procedures performed in the setting of cardiogenic shock.<sup>23</sup> Similarly, our findings support the idea that

documented surgical ineligibility may be an important variable to consider in risk-adjustment models used for hospital quality assessment, given its significant association with PCI outcomes and the likelihood that these patients would be concentrated at institutions that performed cardiac surgery. Many of the surgically ineligible patients that received percutaneous revascularization may have been treated as salvage cases or in the setting of compassionate use, two situations in which the inclusion of surgical ineligibility data could have significant impact on published mortality data and thus clinical practice in states with public reporting of outcomes. The increased anatomical complexity of the surgical ineligible patients supports this notion. In contrast, the surgically eligible patients were found to have lower anatomical complexity suggesting greater clinical equipoise between surgical and percutaneous revascularization thus leading to a large number of eligible patients pursuing PCI. Perhaps this should be considered when evaluating hospital quality and procedural appropriateness.

### Clinical Decision Making

Clinical guidelines and appropriate use criteria have favored surgical revascularization for patients with left main or multivessel coronary artery disease when there is no compelling indication for one treatment modality over the other.<sup>9-11</sup> When a compelling indication may exist, however, the guidelines advocate for a *heart team* approach with input from cardiac surgeons and interventional cardiologists. Interestingly, the present study suggests that formal consultation and electronic documentation from a cardiac surgeon was uncommon in patients with left main or multivessel coronary artery disease undergoing PCI. Perhaps cardiologists treating these patients employed risk prediction instruments such as the STS score or Euroscore to determine the potential morbidity of undergoing surgical revascularization.<sup>24,25</sup> As previously described, these scores aid clinicians in identifying patients that may be high risk for surgical revascularization and thus benefit from a less invasive approach. The data from the present study suggests that increased surgical risk that leads to operative ineligibility does not automatically imply that percutaneous revascularization is a safer option. In fact, addition of surgical ineligibility to similar risk scores developed for percutaneous revascularization suggests increased procedural risk. Further, our data suggest that percutaneous revascularization in these patients results in fewer vessels treated and perhaps greater residual ischemia.

### Limitations

The present study should be interpreted in the context of several limitations. Ascertainment of surgical ineligibility was based upon documentation in the electronic medical record. Because of this, discussions regarding surgical ineligibility that took place during the course of patient care but were not explicitly documented could lead to the misclassification of patients as eligible for surgical revascularization. It is important to note that inclusion of these patients as surgically ineligible would only serve to increase the measured mortality difference between the two populations, rather than demonstrating improved mortality in the ineligible group. Residual confounding between surgical ineligibility and mortality may also exist outside of the collected data. Further, the present analysis does not evaluate differences in outcomes among surgically ineligible patients that are treated medically and those that receive percutaneous revascularization in the setting of disease salvage or compassionate

use. The mortality rates for similar patients treated conservatively may be even higher than those observed with PCI. Finally, the population in this study was gathered from subjects undergoing treatment at two academic tertiary care medical centers and may not be generalizable to other settings. Additional prospective studies including diverse patient populations could be designed to address these limitations.

## Conclusions

In conclusion, documented surgical ineligibility is common and is strongly associated with increased mortality after percutaneous intervention for patients with unprotected left main and multivessel coronary disease, even above and beyond commonly employed risk-adjustment models for percutaneous revascularization.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

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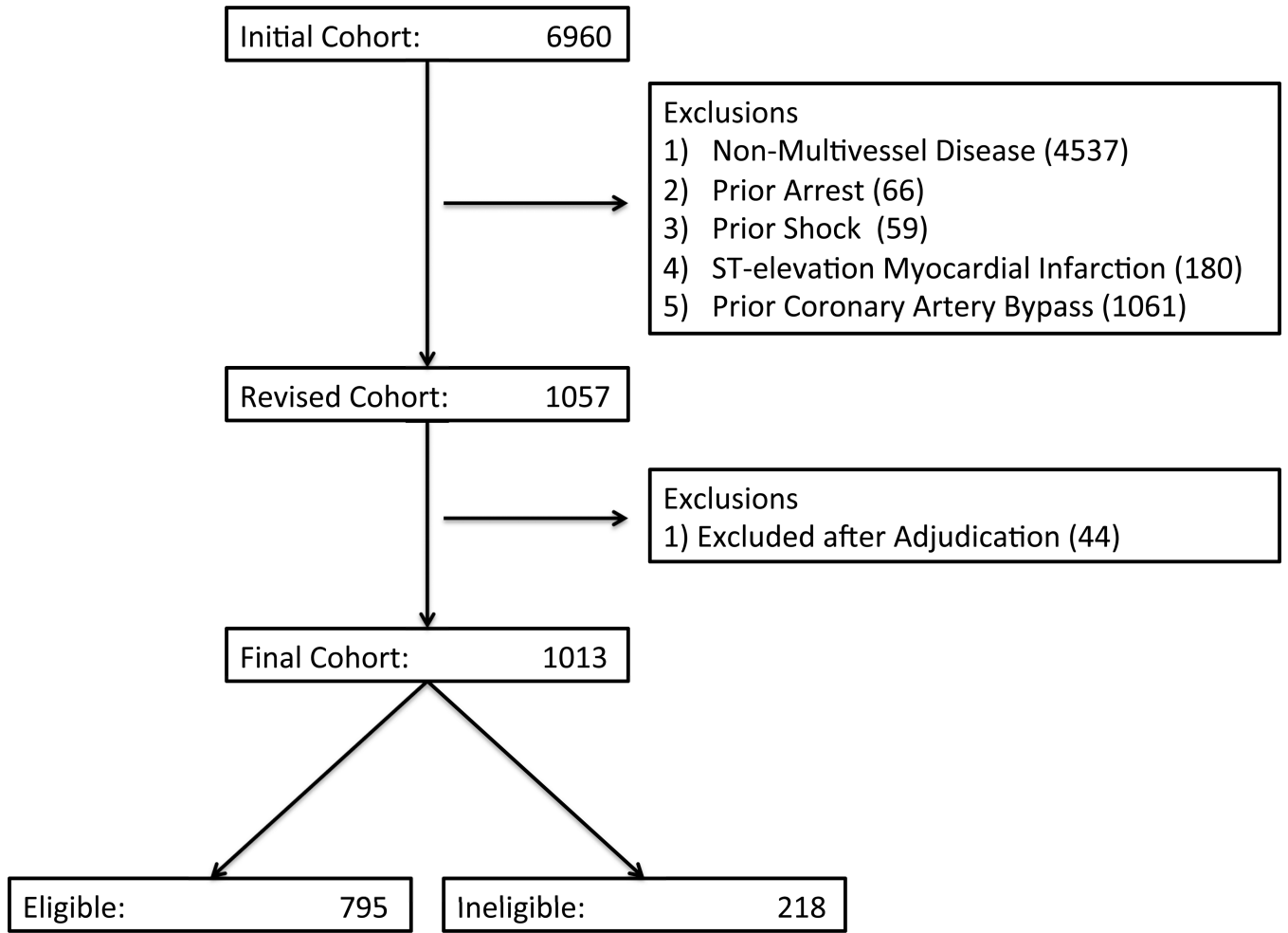
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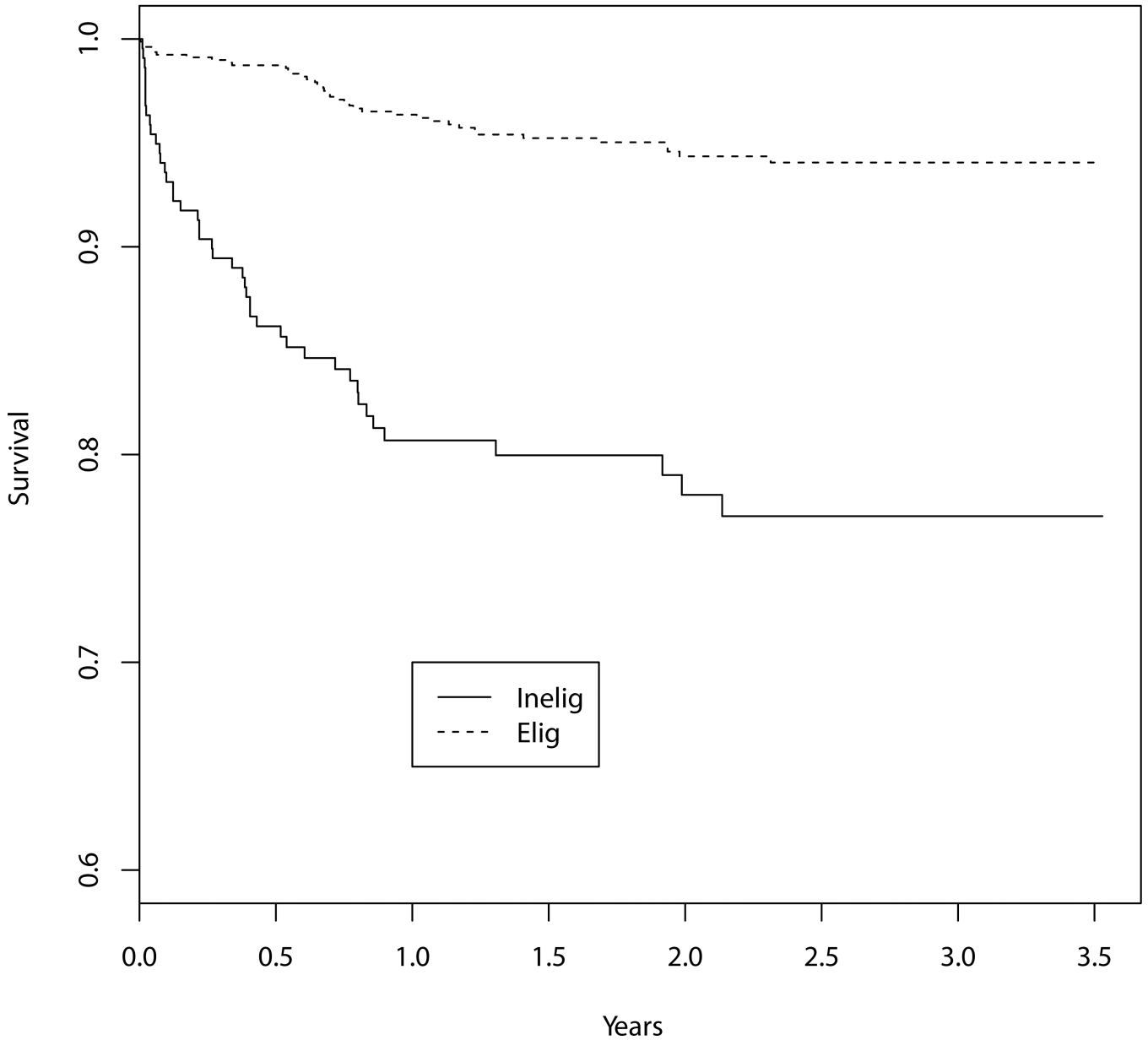
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**Figure 1.** Study Population. Flow-diagram depicting inclusion and exclusion criteria for analysis.

p<.0001



**Figure 2.** Mortality. Kaplan-Meier estimates comparing long-term mortality among those with surgical anatomy undergoing percutaneous revascularization stratified by documentation of surgical ineligibility. Surgical ineligibility (Inelig) was associated with a significant increase in mortality when compared to those that were surgically eligible (Elig, Log-Rank <math>< 0.001</math>).

**Table 1**

## Demographic characteristics.

	<b>Ineligible (n = 218)</b>	<b>Eligible (n = 793)</b>	<b>P-Value</b>
Age (years)	72 ± 12	67 ± 12	<0.001
Male, n (%)	187 (58)	522 (66)	0.039
Race, n (%)			0.117
Asian	9 (4)	22 (3)	
Black	13 (6)	39 (5)	
Hispanic	10 (5)	35 (4)	
Native American	1 (1)	0 (0)	
White	184 (84)	676 (85)	
Other	1 (1)	21 (3)	
Insurance Payer, n (%)			<0.001
Commercial	61 (28)	338 (43)	
Government	154 (71)	445 (56)	
International	0 (0)	3 (1)	
None	3 (1)	7 (1)	
Presenting Symptoms, n (%)			<0.001
No Angina	76 (35)	146 (18)	
Stable Angina	23 (11)	190 (24)	
Unstable Angina	65 (30)	215 (27)	
Non-ST Elevation Myocardial Infarction	49 (22)	223 (28)	
Medical Comorbidities, n (%)			
Cerebrovascular Disease	58 (27)	106 (13)	<0.001
Chronic Lung Disease	65 (30)	110 (14)	<0.001
Congestive Heart Failure	82 (38)	92 (12)	<0.001
Diabetes Mellitus	99 (45)	299 (38)	0.039
Dyslipidemia	205 (94)	741 (93)	0.751
Hypertension	201 (92)	682 (86)	0.015
Peripheral Arterial Disease	78 (36)	120 (15)	<0.001
Prior Myocardial Infarction	114 (52)	244 (31)	<0.001
Prior Percutaneous Intervention	64 (29)	272 (34)	0.170
Valvular Heart Disease	5 (3)	11 (1)	0.342
Laboratory Values			
Glomerular Filtration Rate (ml / min)	62 ± 35	74 ± 28	<0.001
In-Hospital Mortality			
Predicted Mortality (NCDR CathPCI)	0.023 ± 0.034	0.009 ± 0.032	<0.001

All data presented as mean ± standard deviation for continuous variables and number (percentage) for categorical variables

**Table 2**

## Procedural characteristics.

	<b>Ineligible (n = 218)</b>	<b>Eligible (n = 793)</b>	<b>P-Value</b>
Procedural Access, n (%)			<0.001
Femoral	177 (81)	496 (63)	
Radial	34 (16)	263 (33)	
Coronary Anatomy, n (%)			<0.001
Left Main Disease	71 (33)	78 (10)	
Three Vessel Disease	89 (41)	315 (40)	
Two Vessel Disease and proximal LAD	58 (27)	400 (50)	
Coronary Anatomy Complexity, n (%)			
Bifurcation Lesions	8 (4)	48 (6)	0.173
Chronic Total Occlusion	3 (1)	15 (2)	0.610
High Lesion Complexity (Type C)*	110 (51)	272 (34)	<0.001
Coronary Intervention			
Number of Vessels Treated	1.42 ± 0.57	1.57 ± 0.61	<0.001
Number of Lesions Treated	2.00 ± 1.00	1.71 ± 0.87	<0.001
Number of Stents Placed	2.31 ± 1.62	1.87 ± 1.17	<0.001
Total Stent Length (mm)	38 (18 – 64)	30 (18 – 46)	<0.001
Coronary Intervention Vessels, n (%)			
Left Main	47 (22)	39 (5)	<0.001
Left Anterior Descending	135 (62)	523 (66)	0.289
Left Circumflex Coronary Artery	94 (43)	275 (34)	0.022
Right Coronary Artery	62 (28)	278 (35)	0.067
Intra-Aortic Balloon Pump, n (%)	30 (14)	9 (1)	<0.001

All data presented as mean ± standard deviation or median (intraquartile range) for continuous variables and number (percentage) for categorical variables

\* High lesion complexity is defined as a lesion with at least one of the following characteristics: diffuse (length > 2 cm), excessive tortuosity of the proximal segment, extremely angulated segments (> 90 degrees), total occlusions (> 3 months) or inability to protect major side branches.

**Table 3**

Documentation source of surgical ineligibility.

	<b>Ineligible (n = 218)</b>	<b>Eligible (n = 793)</b>	<b>P-Value</b>
Surgical Consult Documentation, n (%)	63 (29)	32 (5)	<0.001
Eligibility Documentation Source, n (%)			<0.001
Cardiology Catheterization Report	43 (21)	40 (5)	
Cardiology Consult Note	77 (37)	50 (6)	
Discharge Summary	50 (24)	35 (4)	
Surgical Consult Note	36 (17)	24 (3)	
None	0 (0)	644 (81)	

**Table 4**

Criteria associated with surgical ineligibility.

	<b>Prevalence</b>
Poor Targets / Conduits, n (%)	52 (24)
Advanced Age, n (%)	35 (16)
Renal Insufficiency, n (%)	35 (16)
Severe Lung Disease, n (%)	32 (15)
Severe Systolic Dysfunction, n (%)	31 (14)
Malignancy, n (%)	24 (11)
Severe Peripheral Arterial Disease, n (%)	17 (8)
Extensive Nonviable Myocardium, n (%)	14 (6)
Severe Aortic Calcification, n (%)	13 (6)
Cachexia, n (%)	9 (4)
Hematologic Abnormality, n (%)	9 (4)
End-Stage Liver Disease, n (%)	8 (4)
Morbid Obesity, n (%)	7 (3)
Severe Cerebrovascular Disease, n (%)	7 (3)
Cognitive Dysfunction, n (%)	6 (3)
Gastrointestinal Bleeding, n (%)	6 (3)
Systemic Infection, n (%)	5 (2)
Chest Wall Abnormality, n (%)	2 (1)
Immunosuppressed, n (%)	2 (1)
Pulmonary Hypertension, n (%)	1 (1)

All data presented as number (percentage) with the total number of patients deemed surgically ineligible (218) used as the denominator.