ORIGINAL RESEARCH

Percutaneous Coronary Intervention Outcomes Based on Decision-Making Capacity

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BACKGROUND: Long-term outcomes of percutaneous coronary intervention (PCI) based on patients' decision-making ability have not been studied. Our objective was to assess long-term outcomes after PCI in patients who provided individual versus surrogate consent.

METHODS AND RESULTS: Data were collected retrospectively for patients who underwent PCI at Cleveland Clinic between January 1, 2015 and December 31, 2016. Inclusion criteria consisted of hospitalized patients aged ≥20 years who had PCI. Patients with outpatient PCI, or major surgery 30 days before or 90 days after PCI, were excluded. Patients who underwent PCI with surrogate consent versus individual consent were matched using the propensity analysis. Kaplan–Meier, log rank, t-statistic, and χ^2 tests were used for statistical analysis. The study was approved by the Institutional Review Board at Cleveland Clinic, Ohio. Of 3136 patients who underwent PCI during the study period, 183 had surrogate consent. Propensity matching yielded 149 patients from each group. Two-year all-cause mortality was significantly higher in the surrogate consent group (38 [25.5%] versus 16 [10.7%] deaths, log-rank χ^2=10.16, P<0.001). The 2-year major adverse cardiac events rate was also significantly higher in the surrogate consent group (60 versus 36 events, log-rank χ^2=8.36, P=0.003).

CONCLUSIONS: Patients with surrogate consent had significantly higher all-cause mortality and higher major adverse cardiac events when compared with patients with individual consent. This study emphasizes the fact that patients with an inability to give consent are at high risk and may need special attention in postprocedural and postdischarge care.

Key Words: coronary angioplasty outcomes ■ informed consent ■ major adverse cardiac events ■ percutaneous coronary intervention ■ surrogate consent

Atherosclerotic coronary artery disease is the most common cause of death.[1] Percutaneous coronary intervention (PCI) is lifesaving in the setting of acute coronary syndromes and improves the quality of life (anginal symptoms[2]) when utilized in the setting of stable coronary artery disease. More than 1 million PCIs are performed every year.[3] Multiple prognostic factors, including age, sex, obesity, and smoking status, have been associated with worse PCI outcomes.[4–9]

Although studies have found that up to 50% of hospitalized patients can lack decision-making capacity as per published literature,[10–12] the role of patients' ability to provide procedural consent on outcomes of PCI remains unknown. A recent study from the American College of Surgeons Geriatric Surgery pilot project demonstrated that surrogate decision-making is associated with a 50% and 30% increased risk of mortality and serious morbidity (including cardiac complications, prolonged ventilation, and infections) among patients

CLINICAL PERSPECTIVE

What Is New?
- Patients who are unable to provide their own consent before percutaneous coronary intervention have higher mortality and major adverse cardiac events at 2 years.

What Are the Clinical Implications?
- This could be indicative of their poor protoplasm and the need for special periprocedural care.

Nonstandard Abbreviations and Acronyms

IC	informed consent
LOS	length of stay
SC	surrogate consent

undergoing general-vascular and orthopedic surgery, respectively.[13] In light of the significant proportion of our hospitalized patients who are at risk of lacking decision-making capacity, we sought to explore the relevance of impaired decision making in the context of percutaneous coronary revascularization. To the best of our knowledge, this is the first study in scientific literature aimed at finding long-term outcomes of PCI in patients who provided individual consent (IC) versus surrogate consent (SC).

METHODS

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Study Design

This retrospective observational study was performed at the Heart and Vascular Institute, Cleveland Clinic, Ohio. It was approved by the Institutional Review Board at Cleveland Clinic. No IC was required for the purpose of this study. No funding was associated with the study. PCI registry at the Cleveland Clinic was used to find patient population, and electronic medical records were used for data collection.

Study Population

Patients who underwent PCI between January 1, 2015 and December 31, 2016 were selected for the study. PCI encounters from the study period were reviewed to include adult patients aged ≥20 years who received PCI during hospitalization (as inpatient status). Patients who underwent outpatient PCI or diagnostic coronary angiography alone were excluded. Patients who had major intrathoracic or intraabdominal surgery 30 days before or 90 days after PCI were excluded from the study to remove the impact of surgery and reduce confounding. Medical records of patients who satisfied eligibility criteria were reviewed to find cases that had SC versus IC before PCI. For patients with multiple interventions, the first PCI encounter with SC was considered as an index visit. For the IC group, the first PCI encounter as per chronological order was selected as an index visit. Baseline data were collected for multiple variables including age, sex, smoking, hypertension, hyperlipidemia, body mass index, diabetes mellitus, chronic lung disease, ESRD, prior history of coronary artery disease, prior history of PCI, prior history of coronary artery bypass grafting, prior history of cerebrovascular disease, prior history of congestive heart failure, and prior history of peripheral artery disease.

The primary outcomes of our study were 2-year all-cause mortality and major adverse cardiovascular events (MACE; a composite of all-cause mortality, acute coronary syndromes [ACS], new-onset end-stage renal disease [ESRD], and stroke). Secondary outcomes included mean survival, rate of recurrence of ACS, new onset of ESRD, stroke or cerebrovascular accidents, and length of stay for index hospitalization (LOS). Indication for PCI was identified and stratified as stable angina, unstable angina, non–ST-segment–elevation myocardial infarction, and ST-segment–elevation myocardial infarction. Data were collected for additional variables including Braden[14] and Morse[15] scores during hospitalization, the reason for SC, causes of death, periprocedural left ventricular ejection fraction, hemoglobin and serum creatinine values before PCI, hospitalization location (intensive care unit versus regular nursing floor), and hospital discharge disposition.

Statistical Analysis

Propensity score matching was utilized to reduce heterogeneity between the 2 cohorts. Propensity score matching was conditioned on demographics and comorbidities shown in Table 1. Propensity scores were estimated using a nonparsimonious multivariable regression model using R Studio (v 3.6.2). In the model, "Consent group" was used as the dependent variable, and age, sex, body mass index, smoking history, hypertension, hyperlipidemia, diabetes mellitus, chronic lung disease, ESRD, family history of coronary artery disease, prior myocardial infarction, prior coronary artery bypass grafting, prior cerebrovascular accidents, prior congestive heart failure, prior peripheral artery disease, and prior PCI were used as covariates. Using a 1:1 greedy matching algorithm

Table 1. Baseline Patient Characteristics With Propensity Score Analysis

Variable	Individual consent (n=149)	Surrogate consent (n=149)	P value	Absolute standardized difference before PSM	Absolute standardized difference after PSM
Age, y	67 (σ=12.1)	67 (σ=12.7)		−0.020	0.013
Men	82 (55)	85 (57)	0.81	0.26	−0.02
Smoking history	34 (23)	31 (21)	0.78	−0.048	−0.049
Body mass index, kg/m^2	30.5 (σ=7.0)	30.3 (σ=6.5)	…	−0.14	0.02
Hypertension	129 (87)	130 (87)	0.90	−0.07	−0.059
Hyperlipidemia	128 (86)	126 (85)	0.87	−0.146	−0.055
Diabetes mellitus	68 (46)	79 (53)	0.90	0.099	0.094
Chronic lung disease	30 (20)	29 (19)	0.99	0.088	0.017
Endstage renal disease	6 (4)	8 (5)	0.78	0.113	0.089
Family history of CAD	23 (15)	25 (17)	0.87	−0.294	−0.035
Prior MI	44 (30)	47 (32)	0.80	0.005	0.028
Prior CABG	8 (5)	11 (7)	0.63	−0.700	0.051
Prior CVA	34 (23)	32 (22)	0.88	0.053	0.000
Prior CHF	44 (30)	53 (36)	0.32	0.157	−0.056
Prior PAD	30 (20)	25 (17)	0.87	−0.015	0.179
Prior PCI	41 (28)	42 (28)	0.99	−0.14	0.029

Data are presented as number (percentage) for categorical variables and mean (SD) for continuous variables. CABG indicates coronary artery bypass graft; CAD, coronary artery disease; CHF, congestive heart failure; CVA, cerebrovascular accident; MI, myocardial infarction; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; and PSM, propensity score matching.

and caliper width of 0.1, we matched 149 patients who had SC with 149 patients who were IC before PCI. We examined absolute standardized differences (ASD) for each variable between the 2 groups to assess the variable balance of the propensity score model (Table 1). Covariate balance and distributional balance for unadjusted and adjusted sample are shown in Figure S1. Propensity score analysis was performed on baseline data to match patients in SC and IC groups to remove confounders and biases to the maximum possible extent for the study design.[16] Estimates of cumulative event rates were calculated by the Kaplan–Meier method[17] and assessed by stratified log-rank analysis.[18] Categorical variables were compared by the χ^2 test, and continuous variables were compared by t test and z test statistics. Stata-16 software was used for statistical analysis.

RESULTS

Patient Population

A total of 3136 hospitalized patients underwent inpatient PCI at the Cleveland Clinic between January 1, 2015 and December 31, 2016. Overall, 112 patients were excluded from the study for not fulfilling eligibility criteria. Of the remaining 3024 subjects, 183 patients had SC, and 2841 patients provided IC before PCI. Propensity score matching yielded 149 patients in each group (Figure 1). The median age of patients who provided IC and SC was 67 years (range, 37–93)

and 67 years (32–93), respectively. SC and IC groups comprised 57% and 55% men, respectively. The mean periprocedural ejection fraction of patients who had IC and SC was 49% (median 52) and 45% (median 47), respectively, with no significant mean difference (4%, 95% CI, 0.9–7.1). The mean number of stents in the IC and SC groups was 1.49 (interquartile range, 1–2) and 1.65 (interquartile range, 1–2), respectively, with no significant mean difference (0.16, 95% CI, −0.2 to 0.35). Remaining baseline characteristics including smoking, hypertension, hyperlipidemia, body mass index, diabetes mellitus, chronic lung disease, ESRD, prior history of coronary artery disease, prior history of PCI, prior history of coronary artery bypass grafting, prior history of cerebrovascular disease, prior history of congestive heart failure, and prior history of peripheral artery disease were also similar between groups (Table 1). The underlying reasons for SC were altered mental status (n=43), active severe ACS symptoms (n=36), intubated and sedated patients (n=25), documented diagnosis of dementia, (n=9), and unknown (n=36). (Table 2).

Primary Outcomes
All-Cause Mortality

A total of 54 patients died during 2 years of follow-up post PCI, 6 of whom withdrew care. The SC group had 38 deaths, whereas 16 died in the IC group. Mortality incidence rates were 179 versus 70 per 1000 person-years in SC and IC groups, respectively. Two-year all-cause mortality was significantly higher in the SC
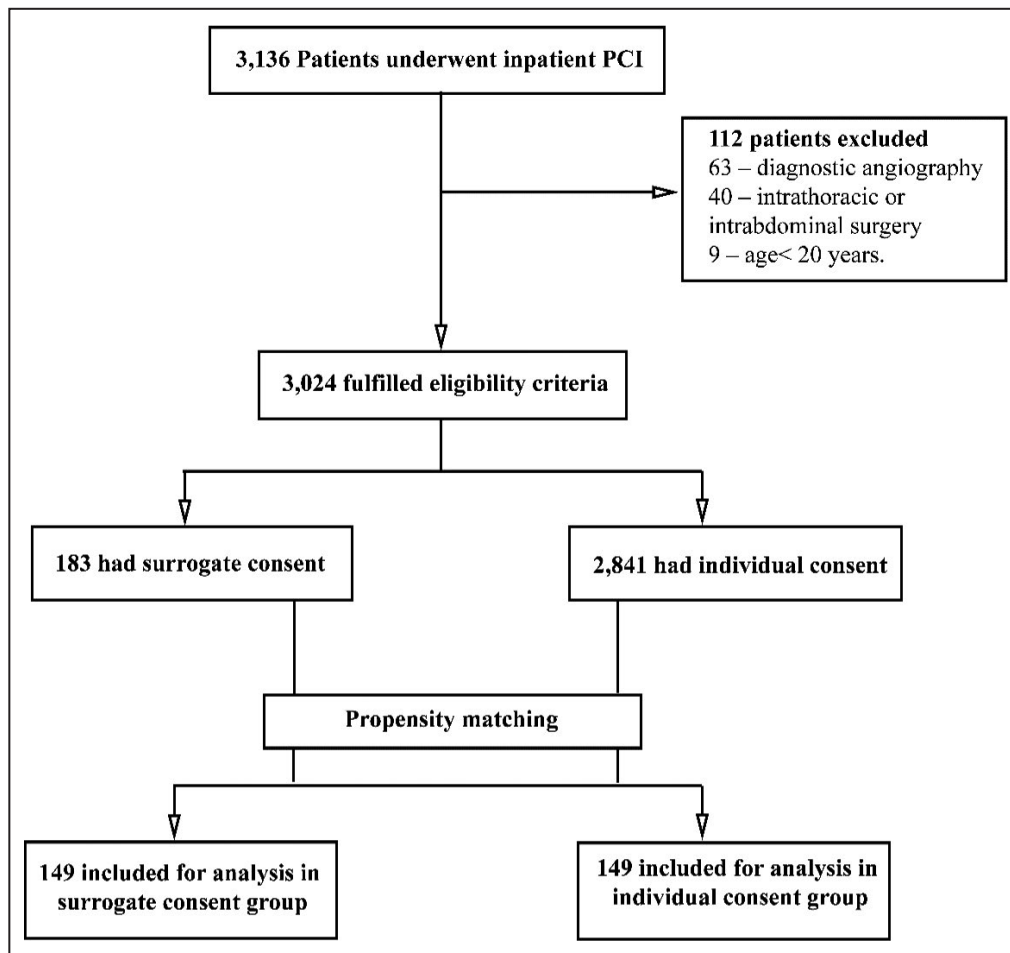
Figure 1.   Study population.
Of 3136 patients who underwent inpatient percutaneous coronary intervention, 112 were excluded from the study for not fulfilling eligibility criteria. A total of 3024 patients met all inclusion criteria. Of these, 183 had surrogate consent and 2841 individual consent. Propensity score matching yielded 149 patients for analysis in each group. PCI indicates percutaneous coronary intervention.

group with a cumulative risk of 25.5% versus 10.7%, log-rank χ^2=10.16, P<0.001. Two-year all-cause mortality remained significantly higher in the SC cohort even after stratification (adjustment) for the indication for PCI, age of the patient, prior history of heart failure,

Table 2.   Underlying Reasons for Providing Surrogate Consent (n=149)

No.	Underlying reasons	No. of patients (percent)
1	Altered mental status	43 (29)
2	Active ACS symptoms	36 (24)
3	Intubated and sedated	25 (17)
4	Documented diagnosis of dementia	9 (6)
5	Unknown	36 (24)

Data presented as number (percentage). ACS indicates acute coronary syndrome.

and prior history of PCI (log-rank χ^2=9.35, P=0.002), showing robustness. Two-year all-cause mortality difference remained statistically significant even after excluding intubated and sedated patients (log-rank χ^2=4.83, P=0.02).

On landmark analysis, 0 to 30-day mortality was significantly higher in the SC group (19 versus 0 deaths, cumulative risk 12.7% versus 0%; log-rank χ^2=19.16, P<0.001). From 31 days to 2 years, 19 versus 16 patients died in the SC and IC groups, respectively (cumulative risk 14.9% versus 11.8%). However, mortality difference failed to reach statistical significance (log-rank χ^2=0.54, P=0.46). Among those who were hospitalized in the intensive care unit, 2-year all-cause mortality remained significantly higher in those who provided SC relative to IC (34 versus 4 deaths, log-rank χ^2=9.81, P=0.001). However, SC patients who did not require intensive care unit stay failed to show a mortality difference (4 versus 12 deaths, log-rank χ^2=0.03, P=0.87). Kaplan–Meier

survival estimates of 2-year mortality are shown in Figure 2. The underlying cause of death was cardiovascular (65%), noncardiovascular (15%), withdrawal of care (11%), and unknown (9%) (Figure 3).

Major Adverse Cardiovascular Events

Among patients who provided SC compared with IC, composite MACE was significantly higher at 2 years with a cumulative risk of 40.3% versus 24.1%, respectively, and incidence rate of 327 versus 174 events per 1000 person-years, respectively (log-rank χ^2=8.36, P=0.003), demonstrated in Figure 4.

Secondary Outcomes

SC and IC groups did not show statistical significant difference in the risk of recurrent ACS at 2 years (incidence rate 133 versus 91/1000 person-years; cumulative risk 16.7% versus 12.7%; log rank χ^2=1.53, P=0.21) (Figure 5). Additionally, the risks of developing ESRD (incidence rate 28 versus 4/1000 person-years; cumulative risk 4.0% versus 0.6%; log-rank χ^2=3.74, P=0.053) and stroke (incidence rate 14 versus 4.3/1000 person-years; cumulative risk 2.0% versus 0.6%; log-rank χ^2=1.09, P=0.29) were not significantly higher in the SC group.

Yet among the SC group, mean survival was significantly lower (141 versus 333 days, mean difference 192 days, [95% CI, 68–315], P=0.003) (Figure 6), and mean LOS was significantly higher (12.7 versus 6 days, mean difference 6.7 days, [95% CI, 4.0–9.3], P<0.001) (Figure 7). Of 149 patients with SC compared with IC, 16 versus 0 died while hospitalized, 4 versus 0 were discharged to inpatient hospice, 19 versus 4 required skilled nursing facility, 9 versus 3 required acute rehabilitation, and 101 versus 142 were discharged home, respectively. Level-of-care requirements and discharge disposition remained significantly different between SC and IC groups (Pearson χ^2=39.7, P<0.001).

Braden and Morse scores were analyzed between groups to determine functional capacity. The SC cohort demonstrated significantly lower mean Braden score (17.5 versus 20.0, mean difference 2.5 [95% CI, 1.81–3.26], P<0.001), but similar mean Morse score (46.7 versus 42.7, mean difference 4.0 [95% CI, 0.08–7.66], P=0.055) compared with the IC group. Furthermore, no significant differences between SC and IC groups were found in mean hemoglobin level (12.5 versus 12.9 mg/dL, respectively, P=0.19) or mean serum creatinine level (1.46 versus 1.38 mg/dL, respectively, P=0.59).

DISCUSSION

In this observational cohort study, patients who were unable to provide individual procedural consent,
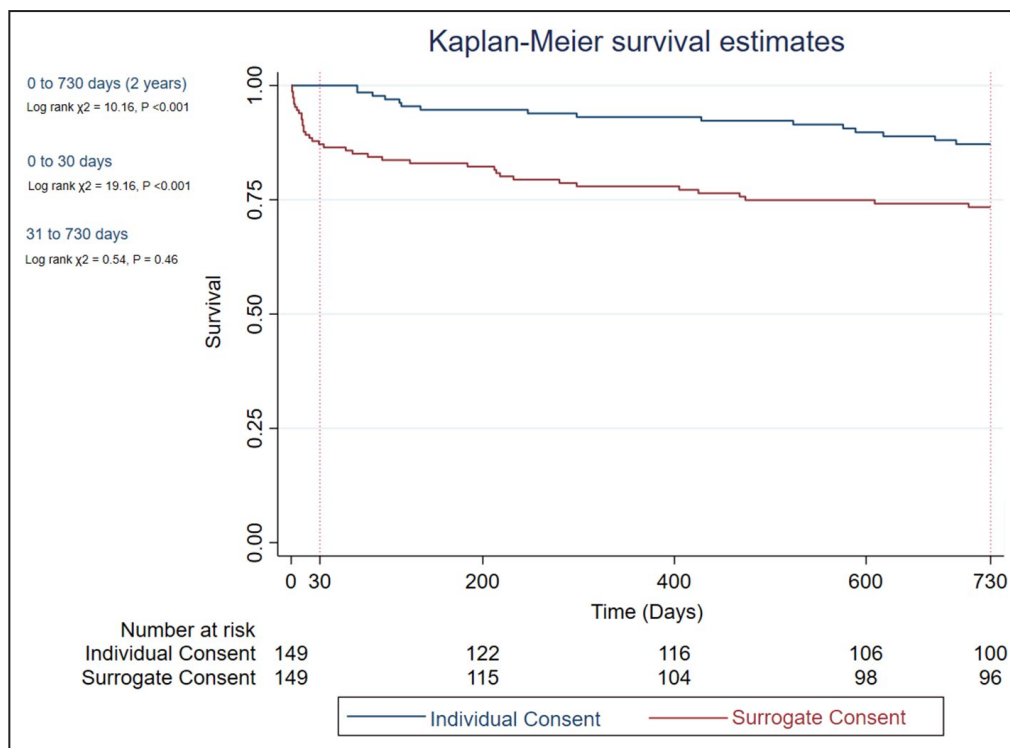

Figure 2. Kaplan–Meier survival estimates.
The plot of survival function shows the difference in survival up to 2 years post percutaneous coronary intervention between patients with surrogate consent (red) and individual consent (blue).
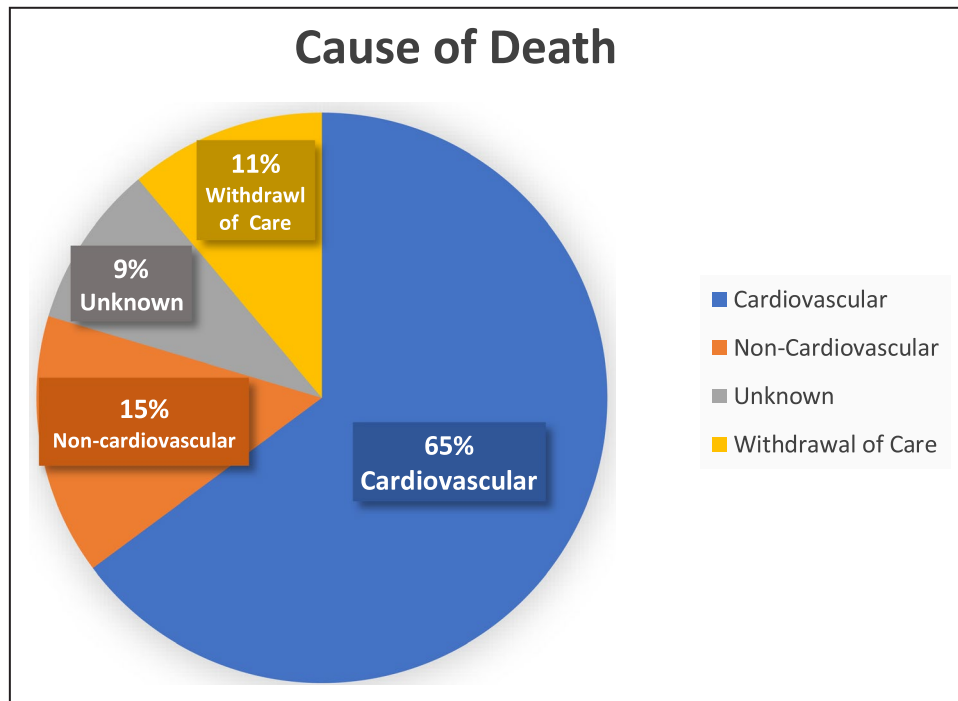
Figure 3. Underlying causes of death.
The pie chart shows the underlying causes of death in the study population with percentages.

comprising 6% of our hospitalized PCI patients, were found to have significantly worse all-cause mortality and combined MACE at 2 years after PCI. While survival estimates remained significantly different up to 2 years, those who required SC revealed the sharpest decline in survival in the early postprocedural phase, suggesting that a poor health protoplasm may have increasingly exacerbated an acute insult. However, the mortality difference remained significant even after excluding critically ill intubated and sedated patients. This adds to the validity of our study and to the fact that the

difference in outcomes was not because of critically ill patients. Our findings reflect IC as a surrogate of health protoplasm and a potential prognostic factor for outcomes of PCI in the hospitalized setting.

Landmark analysis showed significantly higher mortality in the SC group from 0 to 30 days, while the mortality difference between 31 days and 2 years was not statistically significant. It is conceivable that worse short-term outcomes in patients requiring SC may be because of their reduced ability to tolerate cardiac insult and procedural stress, including hospitalization, because of their unaccounted poorer baseline status. The acute component is evidenced by the most common reasons for obtaining SC, which comprises the following possible causes: altered mental status, followed by severe distress because of ACS symptoms, intubation and sedation, and dementia. Furthermore, subgroup analysis of survival estimates demonstrated significantly higher mortality among SC patients requiring a stay in the intensive care unit but not the regular nursing floor, supporting the claim that patients with SC were tenably more comorbid and necessitated higher levels of care at baseline. Mean survival was also significantly shorter in the SC group, suggesting poor life expectancy. Higher all-cause mortality, MACE, and lower mean survival in patients with SC suggest overall worse clinical outcomes. These findings call for greater preprocedural optimization and increased attention in the early postprocedural phase for this patient population.
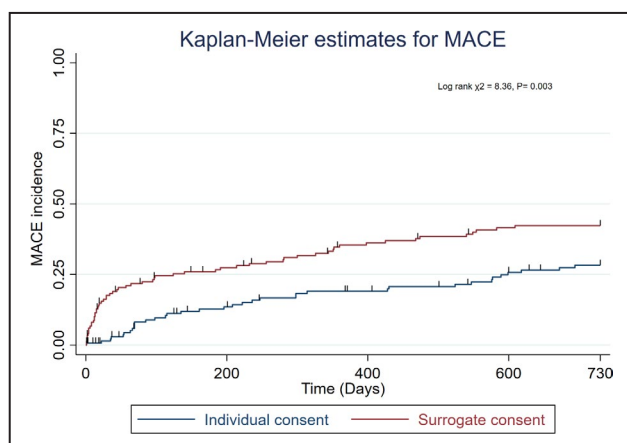

Figure 4. Kaplan–Meier estimates for major adverse cardiac events.
The difference in major adverse cardiac events (MACE) between surrogate (red) vs individual consent group (blue).
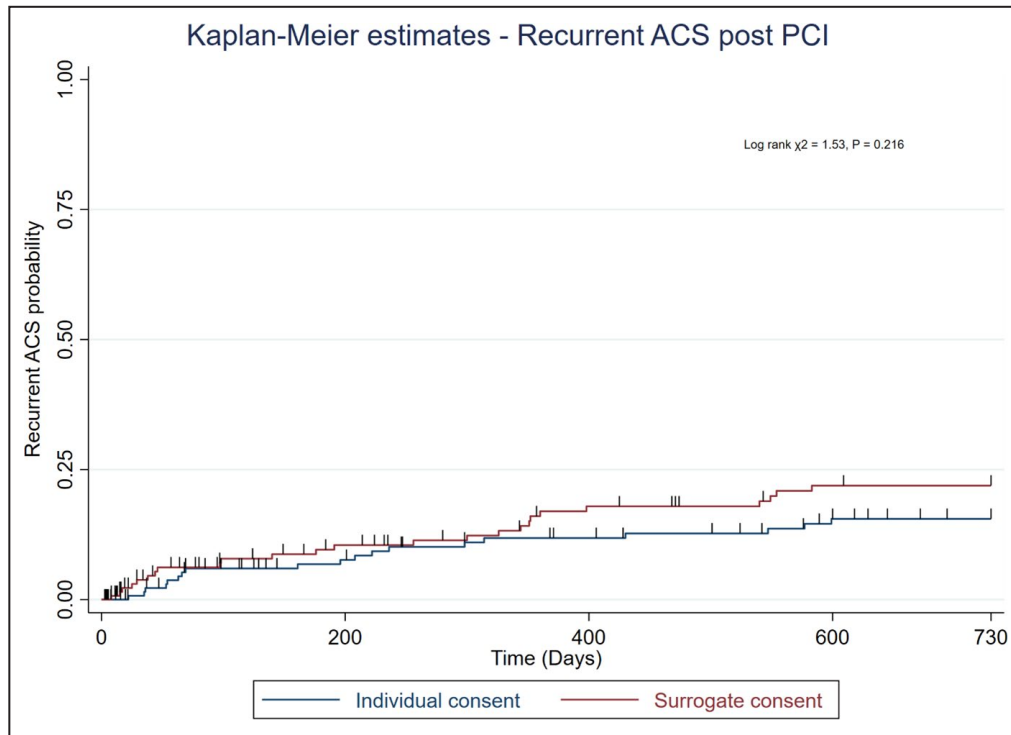
Figure 5. Kaplan–Meier estimates for recurrence of acute coronary syndromes.
Plot showing the probability of recurrence of the acute coronary syndrome (ACS) for surrogate consent (red) vs individual consent group (blue). PCI indicates percutaneous coronary intervention.

Per the American Hospital Association, the average LOS among patients in community hospitals was 5.5 days in 2016,[19] which is consistent with that of patients who were able to provide IC (mean=6 days) in our study. Yet among those with SC, the mean LOS was notably higher at 12.7 days. Longer LOS shows the requirement of more extended in-hospital care

for patients with an inability to give their own consent. Additionally, patients with SC comprised a higher proportion of discharges to nursing homes, rehabilitation centers, and hospice care. Importantly, those with SC further revealed a lower mean Braden score, a measure of the risk of developing a pressure ulcer and indirectly, an indicator of functional status. These findings provide
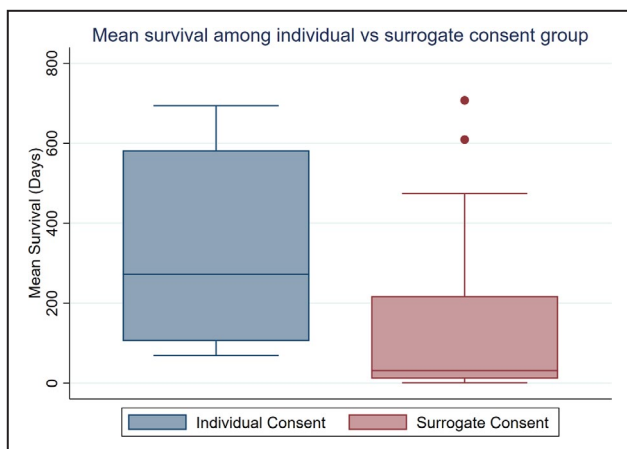

Figure 6. Mean survival in surrogate and individual consent groups.
The mean survival of patients with a surrogate (red) vs individual consent (blue) is shown in the boxplot.
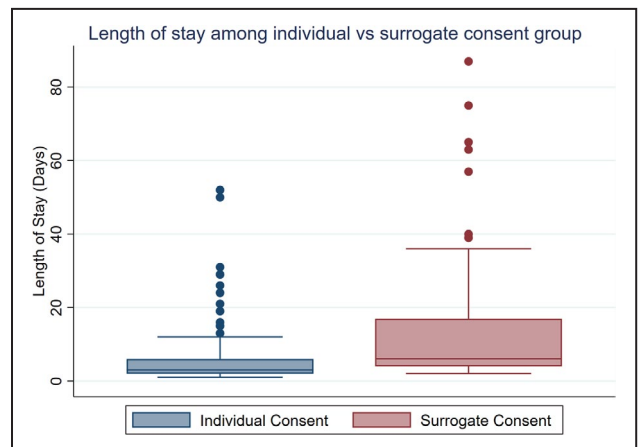

Figure 7. Mean length of stay in surrogate and individual consent group.
The boxplot shows the difference in index hospitalization length of stay for surrogate consent (red) vs individual consent group (blue).

further evidence that those who are unable to consent on their own are tenably at increased baseline risk and more prone to the inherent risks of PCI. The higher level of healthcare requirements during and posthospitalization among this cohort has major clinical and financial implications for institutions and providers alike.

PCI, which is well known to confer mortality benefit over conservative management in patients with ACS,[20–22] has also been shown to relieve symptoms in those presenting with stable angina.[2,23,24] Factors predicting higher mortality and morbidity after PCI are well established,[25–28] yet the impact of decision-making capacity, in the form of procedural consent, on PCI outcomes is unknown but imperative because both the demand and healthcare expenditure are projected to increase in coming years because of disproportionate aging.[29–32] Our limited knowledge on outcomes of patients without preprocedural decision-making capacity warrants further elucidation of its prognostic role in order to better risk-stratify and manage patients.

While no similar studies exist in the cardiovascular literature, prior data from the American College of Surgeons National Surgical Quality Improvement Program Geriatric Surgery Pilot Study showed similar findings of increased odds of mortality in those with SC who underwent nonemergent general or orthopedic surgeries.[13,33] Prior research on IC among those undergoing coronary angiography solely focuses on aspects of comprehension and retention of the consenting process.[34,35] This is the first study that emphasizes IC playing a predictive role in the PCI outcomes. While our findings pose an additive risk in weighing the decision to proceed with PCI, this is hypothesis-generating, and a broader investigation outside the scope of this study is required to better understand the causative factors related to the shown mortality differential and to develop a risk stratification model identifying those who will benefit least from PCI. The benefit of performing PCI in patients with SC and its cost-effectiveness also deserves further exploration. Future work should additionally focus on methods of improving healthcare delivery amidst communication and logistic barriers in populations unable to provide procedural consent.

Limitations

This is a retrospective observational study. It has inherent biases because of study design and cannot be used to make causal inferences. We performed the propensity score matching to mimic aspects of randomization and remove confounders. Although differences in outcomes persisted after matching between selected cohorts, highlighting its appropriateness, we cannot entirely eliminate the confounding effect. Additionally, our single-center study was limited by

a small sample size leading to fewer overall events, which may have explained the lack of mortality difference between 31 days and 2 years, as well as the similar rates of recurrent ACS, stroke, and new-onset ESRD between SC and IC patient groups. Our study had 6% of patients with SC, whereas previous studies show 18% to 50% of hospitalized patients to lack capacity. This could be because our study included an ACS-specific patient population and not a pan-hospital population. Additionally, because of the retrospective nature of the study, we could not assess specifically for the prehospital frailty of the patients.

CONCLUSIONS

In summary, patients who required surrogate consent for PCI had worse outcomes compared with those who provided their own consent, evidenced by higher 2-year all-cause mortality and MACE, shorter mean survival, longer average duration of hospitalization, and increased level of care upon hospital discharge. This all implies a poor health protoplasm in the SC group patients. Further research is needed to determine underlying sources of these poor outcomes and to better risk stratify those who will benefit most from PCI.

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SUPPLEMENTAL MATERIAL

Figure S1. Propensity score matching analysis.
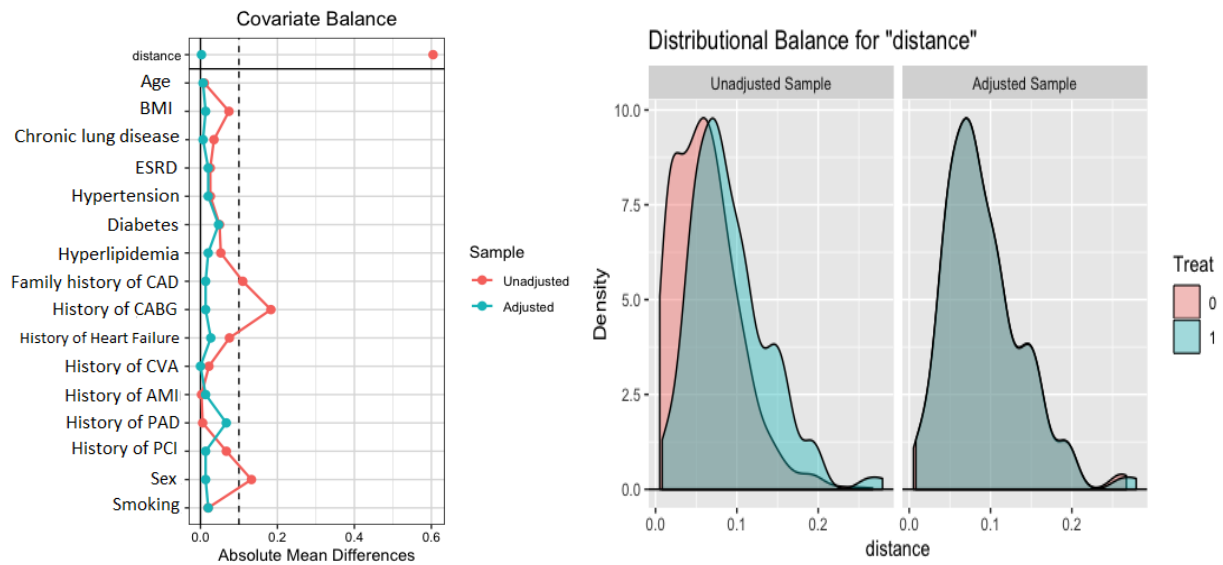
CAD, coronary artery disease; MI, myocardial infarction; CABG, coronary artery bypass graft;

CVA, cerebrovascular accident; CHF, congestive heart failure; PAD, peripheral artery disease;

PCI, percutaneous coronary intervention.