

Usefulness of Intra-aortic Balloon Pump in Patients With Cardiogenic Shock



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Predictors of survival in cardiogenic shock (CS) treated with intra-aortic balloon pump (IABP) are not clearly understood. In this retrospective study, we sought to evaluate patient characteristics and impact of timing of IABP in treatment of CS. Patients presenting to the Yale New Haven Hospital in CS who received IABP between February 2013 and April 2017 were included in the study. We assessed baseline characteristics and clinical predictors of 30-day mortality. Hundred ninety-three (n = 193) patients were included in this study. Mean age was 68.8 ± 14.5 years. Thirty percent (30%) were women, 38% had cardiac arrest, and left ventricular ejection fraction was $33.7 \pm 14.9\%$. Overall 30-day mortality was 36%. Thirty-day mortality was 24% when IABP was placed within less than 1 hour of onset of CS versus 49% when implanted ≥ 1 hour after recognition of CS ($p = 0.001$). Mortality was 18%, 21%, 36%, and 74% for patient requiring 0, 1, 2, and 3 or more inotropes after IABP placement ($p < 0.001$). In multivariate analysis, advancing age, cardiac arrest on presentation, time to IABP implantation, and number of inotropes needed after IABP implantation predicted 30-day mortality. In the 193 patients, 134 (69.4%) presented with CS from ACS and 59 (30.6%) with CS from non-ACS-related causes. No difference in mortality was noted between the ACS and non-ACS groups 34.3% versus 40.7% ($p = 0.39$). In conclusion, early use of IABP in CS was associated with significant improvement in 30-day mortality regardless of the etiology of CS. Continued need for significant inotropic support after IABP is associated with worse prognosis and maybe used as an indicator for need to escalate to higher levels of support. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:750–756)

Intra-aortic balloon pump (IABP) is commonly used for supporting patients with cardiogenic shock (CS).¹ In addition to its favorable effects on left ventricular stroke work, cardiac index, and myocardial oxygen supply demand ratio,² IABP also has some technical advantages such as ease of implantation, greater familiarity, lower cost, and lower complications compared with other temporary mechanical circulatory support devices (TMCS).^{3–5} Despite overall neutral effects of IABP in CS from ACS,⁶ subgroup analysis of IABP SHOCK II trial found younger patients without hypertension or previous myocardial infarction to benefit from IABP.⁶ Identifying predictors of response to IABP could help appropriate device selection. Role of early TMCS placement in CS^{7,8} is being investigated, whereas such data are lacking with IABP. There is also paucity of data with regards to efficacy of IABP in non-ACS CS.^{9,10} In this study, we evaluated the role of IABP in patients with CS (both ACS and non-ACS) and identify predictors of mortality. We hypothesized that timely use of IABP in early stages of shock would improve outcomes.

Methods

Patients with CS, who were supported with IABP between February 2013 and April 2017, were identified at Yale New Haven Hospital. CS was defined by the presence of following clinical or hemodynamic criteria: (1) systolic blood pressure < 90 mm Hg or the need for vasopressor and/or inotropic therapy to maintain a systolic blood pressure > 90 mm Hg and (2) signs of organ hypoperfusion (e.g., oliguria/anuria, altered mental status, and/or cold extremities) or cardiac index ≤ 1.8 L/min/m² without support or ≤ 2.2 L/min/m² with support and pulmonary capillary wedge pressure ≥ 18 mm Hg.¹¹ Patients were identified as ACS-related CS, if they presented with clinical evidence of non-ST-segment elevation myocardial infarction or ST-segment elevation myocardial infarction. All other patients were considered to have non-ACS-related CS. Following patients were excluded: those that received IABP for conditions that are not associated with CS, patients who died in the catheterization laboratory, patients whose support was escalated to veno-arterial extracorporeal membrane oxygenation or Impella (Abiomed, Danvers, Massachusetts) immediately after IABP placement and those who had incomplete medical records. The research protocol was approved by the institutional review board at Yale University. **Figure 1** shows the flowchart representing patient selection.

Categorical variables are presented as percentages. Continuous variables with normal distribution are presented as mean \pm standard deviation and those with skewed distribution are presented as median with interquartile range.

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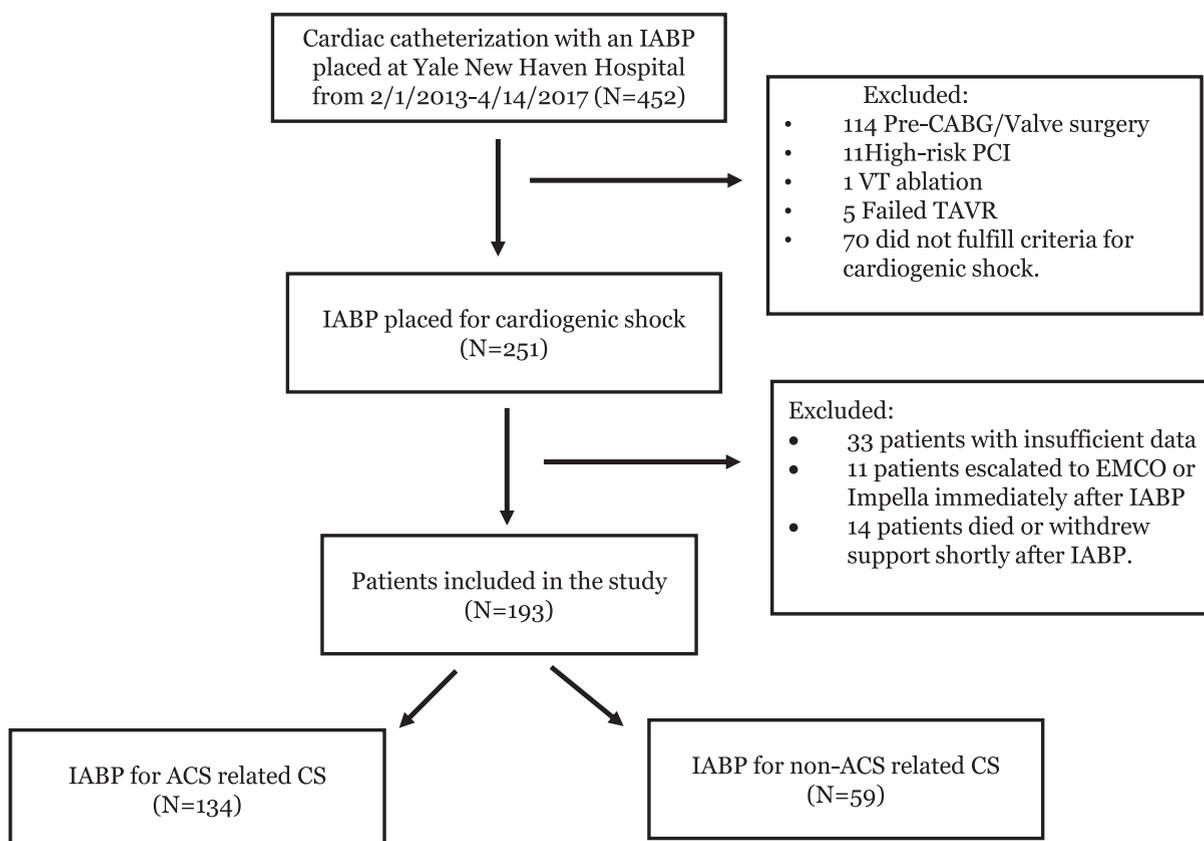


Figure 1. Derivation of study cohort. ACS = acute coronary syndrome; CABG = coronary artery bypass grafting; CS = cardiogenic shock; ECMO = extracorporeal membrane oxygenator; IABP = intra-aortic balloon pump; Impella (Abiomed, Danvers, Massachusetts); non-ACS = nonacute coronary syndrome; PCI = percutaneous coronary intervention; TAVR = transcatheter aortic valve replacement; VT = ventricular tachycardia.

Difference between 2 groups is tested for significance with chi-square tests for categorical variables, *t* tests for continuous variables with normal distribution and with Mann-Whitney for skewed variables. All *p* values were 2-tailed and considered significant when $p \leq 0.05$. Data analysis was performed using IBM SPSS statistics version 24 (IBM Corp., Armonk, New York). Univariate and multivariate binary logistic regression were performed for 30-day mortality as the end point. Cumulative 30-day mortality was assessed using Kaplan-Meier plots using log-rank test to compare between groups.

Results

Baseline characteristics of survivors and nonsurvivors are presented in Table 1. Sixty-nine patients had invasive hemodynamic measurements. These measurements are listed in Table 2. There was no statistically significant difference in invasive hemodynamic parameters between survivors and nonsurvivors. However, cardiac power output was higher in survivors ($p = 0.06$). The median left ventricular ejection fraction was 30% and was not significantly different between survivors and nonsurvivors. Of the 193 patients, 10 patients proceeded to have implantation of durable mechanical circulatory support. Adverse events were observed in 19.6% of this cohort: 6% had bleeding (major or minor), 4.8% had peripheral ischemic

complications, and 8.8% developed sepsis. Six patients had right ventricular infarction and 2 developed complete heart block. One patient had papillary muscle rupture and died within 30 days. Overall 30-day mortality was 36%. Survivors were younger (median age 65 years vs 78 years), less likely to have had cardiac arrest and had lower creatinine on presentation.

Predictors of 30-day mortality based on univariate analysis are shown in Table 3. On multivariate analysis, age, number of inotropes post-IABP, need for CPR, and time-to-IABP use were significant predictors of 30-day mortality (Table 4). Figure 2 displays the increasing 30-day mortality rate with increasing number of inotropes. Mortality was 18%, 21%, 36%, and 74% for patient requiring 0, 1, 2, and 3 or more inotropes after IABP placement ($p < 0.001$). A similar relation was also observed between the time of CS onset and IABP insertion and 30-day mortality. Thirty-day mortality was 24% when IABP was placed within less than 1 hour of onset of CS versus 49% when implanted ≥ 1 hour after recognition of CS ($p = 0.001$; Figure 3). Multivariate regression analysis not including CPR continued to show significant correlation between need for higher inotropic support after IABP placement and increasing time to IABP with higher 30-day mortality.

We derived a risk score based on these predictors. Mortality prediction risk score = 0.06 (age in years) + 0.7 (number of inotropes) + 0.05 (time to IABP in hours) + 0.9

Table 1
Baseline characteristics of patients underwent IABP implantation, stratified by survivors and nonsurvivors

Variables	All (n = 193)	Survivors (n = 123)	Nonsurvivors (n = 70)	p Value*
Age (years)	70 (59-80)	65 (57-76)	78 (64-84)	<0.001 [†]
Women	57/193 (29.5%)	35/123 (28.4%)	22/70 (31.4%)	0.66
Body mass index (kg/m ²)	26.8 (24.2-31.1)	27.3 (24.8-31.6)	25.8 (23.9-29.4)	0.06
Systolic blood pressure (mm Hg)	82 (72-90)	80 (71-88)	82 (73-91)	0.34
Diastolic blood pressure (mm Hg)	53 (46-62)	53 (48-63)	52 (42-60)	0.14
Mean blood pressure (mm Hg)	63 (55-73)	63 (55-73)	61 (53-69)	0.27
Heart rate (bpm)	89 (73-107)	92 (76-109)	83 (67-101)	0.03 [†]
Mechanical ventilation	148/193 (76.7%)	87/123 (70.7%)	61/70 (87%)	0.01 [†]
Cardiopulmonary resuscitation	73/193 (37.8%)	36/123 (29.2%)	37/70 (52.8%)	0.001 [†]
Current smoker	50/192 (26%)	39/123 (31.7%)	11/69 (15.9%)	0.02 [†]
Hypertension	129/193 (66.8%)	82/123 (66.6%)	47/70 (67.1%)	0.95
Hypercholesterolemia	92/192 (47.9%)	60/122 (49.2%)	32/70 (45.7%)	0.64
Diabetes mellitus	72/191 (37.7%)	45/122 (36.9%)	27/69 (39.1%)	0.76
Prior cerebrovascular accident	25/190 (13.2%)	11/121 (9%)	14/69 (20%)	0.03 [†]
Chronic kidney disease	52/188 (27.7%)	33/119 (22.7%)	19/69 (27.5%)	0.98
Creatinine (mg/dl)	1.3 (0.9-1.8)	1.2 (0.9-1.5)	1.7 (1.2-2.5)	<0.001 [†]
Glucose (mg/dl)	187 (132-259)	180 (127-259)	195 (133-265)	0.55
Left ventricular ejection fraction (%)	30 (23-45)	33 (23-45)	25 (22-43)	0.12

Nonparametric data are presented as median with interquartile range.

* Comparing survivors to nonsurvivors.

[†] Statistically significant difference with a p value ≤0.05.

Table 2
Hemodynamics of patients who had invasive hemodynamic monitoring

Variables	All (n = 69)	Survivors (n = 45)	Nonsurvivors (n = 24)	p Value
Central venous pressure (mm Hg)	18 ± 6	17 ± 6	18 ± 6	0.88
Right ventricular systolic pressure (mm Hg)	48 ± 12	47 ± 11	49 ± 12	0.70
Right ventricular diastolic pressure (mm Hg)	16 ± 5	16 ± 5	15 ± 5	0.50
Pulmonary artery systolic pressure (mm Hg)	49 ± 13	50 ± 13	48 ± 12	0.72
Mean pulmonary artery pressure (mm Hg)	37 ± 10	38 ± 11	34 ± 8	0.14
Pulmonary capillary wedge pressure (mm Hg)	28 ± 8	28 ± 7	29 ± 10	0.79
Cardiac index (L/min/m ²)	1.8 ± 7	1.9 ± 0.7	1.7 ± 0.8	0.28
Cardiac power output (W)	0.56 ± 0.2	0.59 ± 0.2	0.48 ± 0.2	0.06

(CPR) — 5.5. Patients were divided into quartiles based on this risk score (Figure 4). Dividing the prediction model into quartiles incorporating these variables shows that mortality increases from 6.1 % in first quartile to 67.4 % in

fourth quartile (p < 0.001). A total of 134 (69.4%) presented with ACS as the etiology of their CS (94 with ST-segment elevation myocardial infarction and 40 with non-ST-segment elevation myocardial infarction). Fifty-nine (30.6%)

Table 3
Variables predicting 30-day mortality on univariate analysis

Variables	Odds ratio	95% Confidence limits	p Value*
Age	1.05	1.03–4.08	0.000
Body mass index	0.94	0.89–0.99	0.038
Mechanical ventilation	0.36	0.16–0.79	0.012
Current smoker	2.45	1.16–5.17	0.019
Prior cerebrovascular accident	0.39	0.17–0.92	0.032
Baseline heart rate	0.99	0.98–1.00	0.067
Baseline creatinine	1.48	1.11–1.98	0.007
Inotropes prior to IABP	1.56	1.15–2.11	0.004
Inotropes post-IABP	2.04	1.55–2.67	0.000
Time to IABP	1.03	1.00–1.05	0.018
Cardiopulmonary resuscitation	0.37	0.2–0.68	0.001

* Statistically significant difference with a p value ≤0.05.

Table 4
Variables predicting 30-day mortality on multivariate analysis

Variables	Odds ratio	95% Confidence limits	p Value*
Age	1.07	1.03–1.10	0.001*
Body mass index	0.93	0.86–1.00	0.054
Mechanical ventilation	1.32	0.43–3.99	0.628
Current smoker	1.12	0.39–3.18	0.826
Prior cerebrovascular accident	2.74	0.94–8.00	0.066
Baseline heart rate	0.99	0.98–1.00	0.313
Baseline creatinine	1.34	0.98–1.82	0.068
Inotropes prior to IABP	1.39	0.88–2.20	0.16
Inotropes post-IABP	2.03	1.44–2.84	0.000*
Time to IABP	1.05	1.01–1.09	0.009*
Cardiopulmonary resuscitation	2.44	1.04–5.72	0.041*

* Statistically significant difference with a p value ≤0.05.

Survival Based on Numbers of Inotropes Needed Post IABP

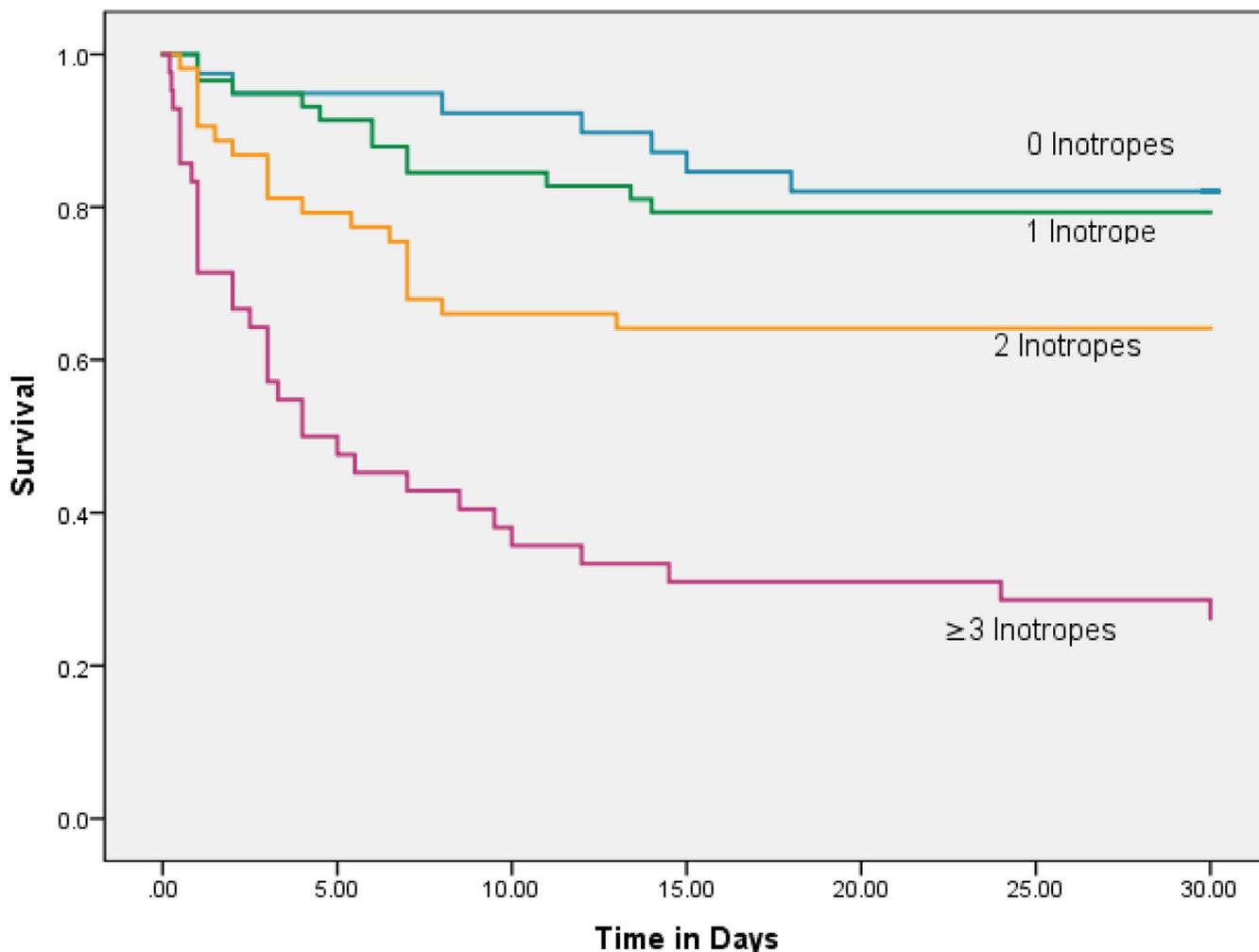


Figure 2. Survival based on number of inotropes needed post-IABP. Kaplan-Meier survival curves stratified by number of inotropes needed after intra-aortic balloon pump placement.

had CS from non-ACS-related causes. Table 5 shows the baseline characteristics of patients presenting with ACS and non-ACS. Patients in the non-ACS group were younger, had higher blood pressure and heart rate at baseline, whereas left ventricular ejection fraction was lower in non-ACS group (25% compared with 35%, $p=0.003$). No difference in survival was noted between the ACS and non-ACS groups (34.3% vs 40.7%, $p=0.39$).

Discussion

Management of CS remains a daunting task with rising number of patients with this diagnosis.¹² Devices such as Impella (Abiomed, Inc., Danvers, Massachusetts) and TandemHeart (Cardiac Assist, Inc., Pittsburgh, Pennsylvania), whereas offering better hemodynamic support, have greater adverse effect.^{5,4} Venous-arterial extracorporeal membrane oxygenation is reserved for sicker patients with biventricular failure and associated with higher morbidity and mortality.^{13,14} Identification of predictors of response to IABP support would allow us to tailor therapy and reserve use of

more powerful TMCS devices for patients that have more advanced stages of CS. The acuity of illness of this patient cohort was similar to that reported in other studies^{12,13} with 30% requiring CPR and 75% of the patients on ventilators. The 30-day mortality in our study is comparable to the reported mortality in IABP-SHOCK II (36% vs 39.7%).⁶ In addition to previously reported indicators of poor outcome,^{15,16} such as age and need for CPR, we also identified that the early use of IABP (less than 1 hour of presentation with CS) and requirement for minimal pressor/inotrope support after the IABP placement were predictors of lower mortality in CS. Although clinical trials use a binary definition to identify the presence of shock, in clinical practice there is a spectrum of presentation for shock. This might in part explain the discrepant results seen in IABP trials.¹⁷ As seen previously,¹⁸ we note that younger patients have a better response to IABP. It has been shown that escalating doses of vasopressors and inotropes are associated with increased mortality.¹⁹ Earlier intervention aiming for shorter "door-to-support" time with Impella has shown benefit.⁷ Our study shows similar results with earlier use of

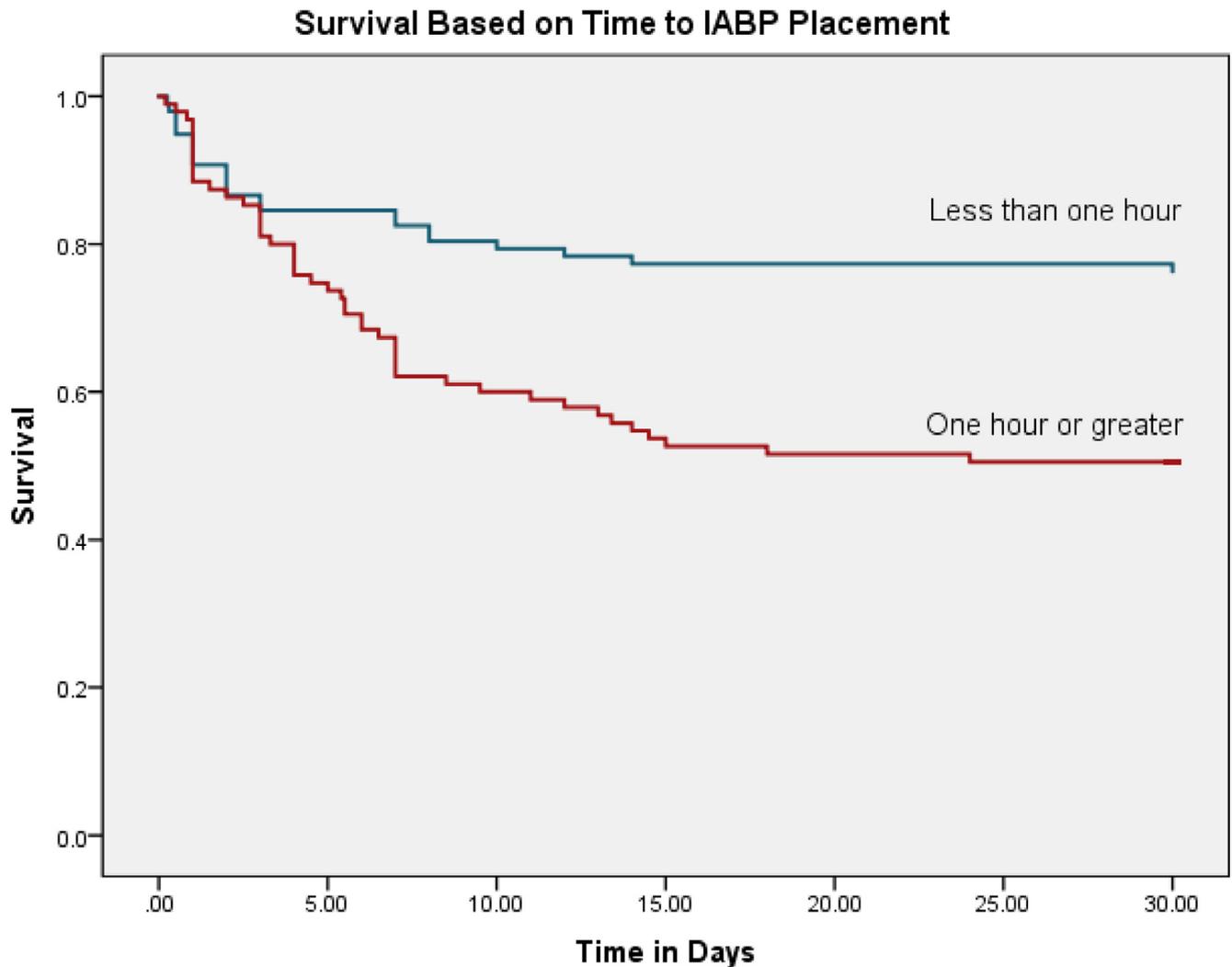


Figure 3. Survival based on time to IABP placement. Kaplan-Meier survival curves stratified by time to intra-aortic balloon pump placement after identification of cardiogenic shock.

IABP. We are also reporting for the first time that ongoing need for high-dose pressors after IABP implantation is a poor prognosticator. In this cohort, patients who required 2 or more pressors after IABP had the worst outcome. Escalation of therapy to devices that can offer greater hemodynamic support should be considered in these patients.

More than 25% of our cohort (59 patients) had CS from non-ACS causes, making this, to our knowledge the largest published clinical dataset including non-ACS CS. Despite different pathophysiological mechanisms the 30-day outcomes are no different between the ACS and non-ACS groups in this cohort. Although ACS is the most common reported etiology of CS, non-ACS-related CS accounts for about 20%¹⁵ of the cases. The CardShock study showed better survival in patients presenting with non-ACS CS (40% in ACS CS vs 24% in non-ACS CS). However, it is unclear if the acuity of illness was similar in the 2 groups as 64% of the ACS compared with 19% of the non-ACS group received IABP support. In our cohort, where IABP was

needed in all the patients there was no difference in mortality in the ACS and non-ACS groups.¹⁵

Finally, IABP associated peripheral ischemic complications in our group was similar to the outcomes reported in SHOCK-IABP II trial (4.8% vs 4.3%),⁶ however, less bleeding and septic shock were observed in our group. This difference may be attributed to the inherent bias related to the nature of the study and different definitions and/or thresholds for these complications.

Some of the limitations of our study are that it is a single-center retrospective analysis. IABP was placed in all the patients and there was no control group. Although we made every effort to ensure that we have the best assessment of time of onset of CS by looking at various documentation sources including initiation of inotropes, documentation of hypotension, and clinical documentation of shock, the retrospective nature of this limits the accuracy of calculation of time to IABP placement. Effect of other unmeasured variables cannot be assessed in this study.

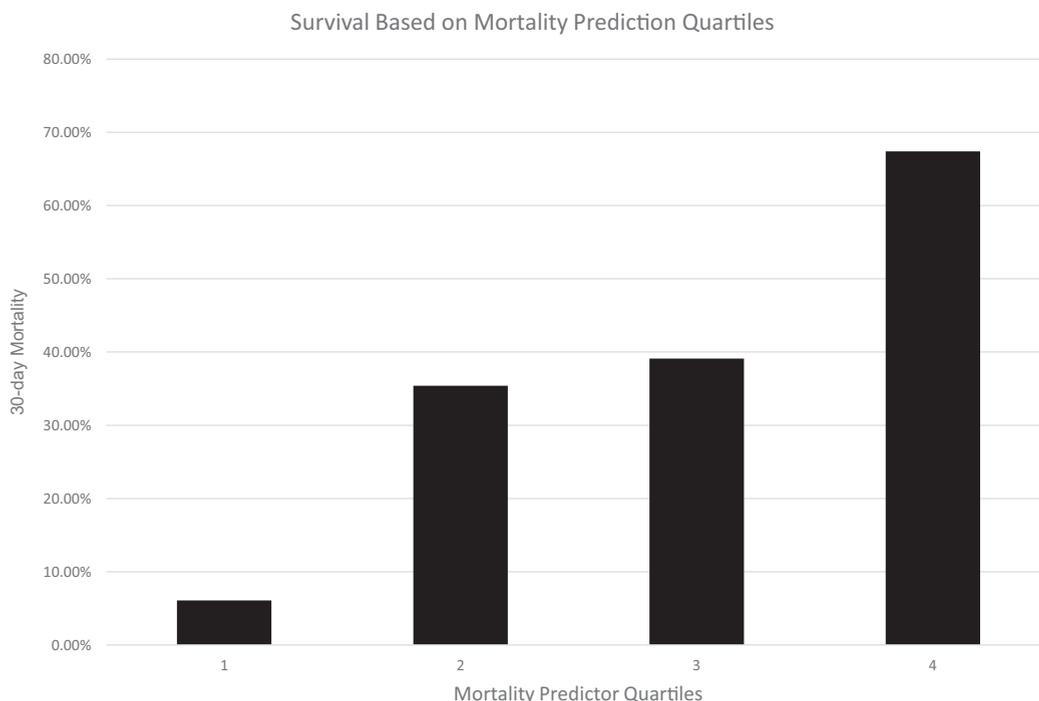


Figure 4. Survival based on mortality prediction quartiles. Thirty-day mortality based on risk stratification using the mortality prediction score. Mortality prediction risk score was calculated using the equation, $0.06(\text{age in years}) + 0.7(\text{number of inotropes}) + 0.05(\text{time to IABP in hours}) + 0.9(\text{CPR}) - 5.5$.

Conclusion

Although randomized control trial data does not show benefit of routine use of IABP in those presenting with CS, the time dependent nature of outcomes with CS and importance of degree of severity of CS was not addressed thus far. The importance of early support is now being evaluated

with favorable outcomes in CS patients using devices such as Impella. In this context, we re-evaluated the utility of IABP, demonstrating earlier use is associated with survival benefit. We also show that need for multiple pressors after IABP placement portends a poor prognosis and should prompt consideration for escalation of support to other TMCS devices that can offer greater support. Our study has

Table 5
Baseline characteristics stratified by presentation, acute coronary syndrome versus nonacute coronary syndrome-related cardiogenic shock

Variables	All (n = 193 patients)	ACS (n = 134)	Non-ACS (n = 59)	p Value
Age (years)	70 (59-80)	73 (62-82)	59 (62-76)	0.001*
Women	57/193 (29.5%)	39/134 (29.1%)	18/59 (30.5%)	0.84
Body mass index (kg/m ²)	26.8 (24.2-31.1)	26.6 (23.8-30.5)	28 (25.2-32.4)	0.06
Systolic blood pressure (mm Hg)	82 (72-90)	79 (71-87)	86 (75-102)	0.002*
Diastolic blood pressure (mm Hg)	53 (46-62)	51 (45-59)	59 (48-69)	0.001*
Mean blood pressure (mm Hg)	63 (55-73)	61 (54-67)	68 (60-84)	<0.001*
Heart rate (bpm)	89 (73-107)	88 (71-102)	98 (78-116)	0.004*
Mechanical ventilation	148/193 (76.7%)	102/134 (76.1%)	46/59 (77.9%)	0.78
Cardiopulmonary resuscitation	73/193 (37.8%)	52/134 (38.8%)	21/59 (35.6%)	0.67
Current smoker	50/192 (26%)	39/133 (29.3%)	11/59 (18.6%)	0.12
Hypertension	129/193 (66.8%)	90/134 (67.2%)	39/59 (66.1%)	0.89
Hypercholesterolemia	92/192 (47.9%)	63/133 (47.4%)	29/59 (49.2%)	0.82
Diabetes mellitus	72/191 (37.7%)	49/134 (36.6%)	23/57 (40.4%)	0.72
Prior cerebrovascular accident	25/190 (13.2%)	18/131 (13.7%)	7/59 (11.9%)	0.55
Chronic kidney disease	52/188 (27.7%)	34/132 (25.8%)	18/56 (32.1%)	0.37
Creatinine (mg/dl)	1.3 (0.9-1.8)	1.25 (0.9-1.8)	1.4 (0.9-2.1)	0.36
Glucose (mg/dl)	187 (132-259)	195 (134-268)	160 (128-252)	0.19
Left ventricular ejection fraction (%)	30 (23-45)	35 (25-45)	25 (20-40)	0.003*

Nonparametric data are presented as median with interquartile range.

* Statistically significant difference with a p value ≤ 0.05 .

the largest reported clinical cohort of CS patients from non-ACS cause and demonstrates the utility of early use of IABP regardless of the etiology of CS.

Disclosures

The investigators have no relevant disclosures or conflict of interest.

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