

ORIGINAL ARTICLE

Clinical characteristics and outcomes of acute coronary syndrome patients with intra-aortic balloon pump inserted in intensive cardiac care unit of a tertiary clinic

Tersiyer bir kliniğin ileri kardiyak bakım ünitesinde intra-aortik balon pompası takılan akut koroner sendromlu hastaların klinik özellikleri ve sonlanımları

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ABSTRACT

Objective: An intra-aortic balloon pump (IABP) is a mechanical support device that is used in addition to pharmacological treatment of the failing heart in intensive cardiac care unit (ICCU) patients. In the literature, there are limited data regarding the clinical characteristics and in-hospital outcomes of acute coronary syndrome patients in Turkey who had an IABP inserted during their ICCU stay. This study is an analysis of the clinical characteristics and outcomes of these acute coronary syndrome patients.

Methods: The data of patients who were admitted to the ICCU between September 2014 and March 2017 were analyzed retrospectively. The data were retrieved from the ICCU electronic database of the clinic. A total of 142 patients treated with IABP were evaluated in the study. All of the patients were in cardiogenic shock following percutaneous coronary intervention, at the time of IABP insertion.

Results: The mean age of the patients was 63.0±9.7 years and 66.2% were male. In-hospital mortality rate of the study population was 54.9%. The patients were divided into 2 groups, consisting of survivors and non-survivors of their hospitalization period. Multivariate analysis after adjustment for the parameters in univariate analysis revealed that ejection fraction, Thrombolysis in Myocardial Infarction flow score of ≤2 after the intervention, chronic renal failure, and serum lactate and glucose levels were independent predictors of in-hospital mortality.

Conclusion: The mortality rate remains high despite IABP support in patients with acute coronary syndrome. Patients who are identified as having a greater risk of mortality according to admission parameters should be further treated with other mechanical circulatory support devices.

ÖZET

Amaç: İntraaortik balon pompasının (İABP) kardiyak yoğun bakım ünitesi (KYBÜ) hastalarındaki kalp pompa yetersizliğinde farmakolojik tedaviye ek destek tedavisi olarak kullanılması kabul görmüş bir uygulamadır. Kardiyak yoğun bakım ünitesine kabul edilen İABP takılmış akut koroner sendromlu hastaların klinik özellikleri ve hastane içi sonuçları hakkında literatürde ülkemiz hakkında sınırlı veri vardır. Çalışmamızda bu akut koroner sendromlu hastaların klinik özelliklerini ve sonuçlarını incelemeyi amaçladık.

Yöntemler: Eylül 2014 ile Mart 2017 arasında KYBÜ'ye kabul edilen hastaların verileri geriye dönük olarak incelendi. Veriler kliniğimizin KYBÜ elektronik veri tabanından elde edildi. İntra-aortik balon pompası takılan 142 hasta çalışmamızda değerlendirildi. Perkütan koroner girişimi takiben, tüm hastalar İABP takılması sırasında kardiyojenik şoktaydı.

Bulgular: Hastaların ortalama yaşı 63.0±9.7 idi ve %66.2'si erkekti. Çalışma grubunun hastane içi mortalitesi %54.9 idi. Hastalar hastanedeki içi mortalitelerine göre hayatta kalanlar ve hayatını kaybedenler olmak üzere ikiye ayrıldı. Tek değişkenli analizdeki parametrelerin kullanımı ile yapılan çok değişkenli analizde ejeksiyon fraksiyonu, perkütan girişim sonrasında TIMI ≤2 akım olması, kronik böbrek yetersizliği, serum laktat ve glukoz düzeyleri hastane içi mortalitenin bağımsız öngördürücüleri olarak saptandı.

Sonuç: Akut koroner sendromlu hastalarda İABP desteğine rağmen mortalite yüksektir. Başvuru parametrelerine göre mortalite bakımından yüksek riskli olarak belirlenmiş hastalar diğer mekanik destek cihazları ile tedavi edilmelidir.

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The well-accepted clinical indications for IABP administration are cardiogenic shock before or after coronary revascularization, high-risk percutaneous revascularization, mechanical complications of myocardial infarction (MI), postoperative pump failure, refractory angina, bridge to cardiac transplantation, and refractory arrhythmias. There are 2 main targets for IABP: to support hemodynamics in cardiogenic shock, and to treat refractory ischemia in patients with coronary artery disease.

IABP use in acute MI has undergone serious change after observational and randomized, controlled, clinical trials. In the beginning, the 2008 European and 2009 American guidelines recommended IABP use as class IC and IB, respectively, in acute MI complicated with cardiogenic shock.^[1,2] Yet, despite solid recommendations in the guidelines, IABP was underused in routine clinical practice, with a 25% to 40% rate worldwide.^[3] The underlying reason for this is considered to be secondary to challenging studies.^[4,5] No 30-day mortality benefit was observed between patients with and without IABP in the Intra-aortic Balloon Pump in Cardiogenic Shock (IABP-SHOCK) trial.^[6] IABP use in MI complicated with cardiogenic shock regressed further in recent guidelines; the 2013 American guidelines recommended it as class IIA, whereas the 2014 European guidelines moved it to class III.^[7,8]

IABP is also recommended as mechanical circulatory support in heart failure patients while bridging to transplantation. Even though a left ventricular assist device (LVAD) is widely recommended under the title of “mechanical circulatory support,” temporary percutaneous support devices such as IABP may serve as a bridge to definite therapy in selected patients, according to the 2016 European Society of Cardiology heart failure guidelines.^[9] The recommendation for

Abbreviations:

CHF	Congestive heart failure
CI	Confidence interval
CRF	Chronic renal failure
DM	Diabetes mellitus
EF	Ejection fraction
HT	Hypertension
IABP	Intra-aortic balloon pump
ICCU	Intensive cardiac care unit
INTERMACS	Interagency Registry for Mechanically Assisted Circulatory Support
LVAD	Left ventricular assist device
MI	Myocardial infarction
OR	Odds ratio
PCI	Percutaneous coronary intervention
TIMI	Thrombolysis in Myocardial Infarction
TTE	Transthoracic echocardiography
WBC	White blood cell

IABP appears in Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) level 1 heart failure patients (crush and burn state), whereas LVAD dominates the guideline by standing in all other INTERMACS levels of patients with advanced heart failure.^[10]

In our country, unfortunately, there are limited data on IABP use in acute coronary syndrome patients. The aim of this study was to evaluate the clinical characteristics and predictors of mortality of 142 patients with an IABP inserted in the intensive cardiac care unit (ICCU) of a tertiary clinic.

METHODS

Study design and patient population

This study was designed as a retrospective, observational, single-center study. The data of patients who were admitted to the ICCU between September 2014 and March 2017 were analyzed. A total of 142 acute coronary syndrome patients treated with an IABP (1.78%) were assessed. All of the patients were evaluated using demographic parameters, routine biochemistry, complete blood count, electrocardiography, transthoracic echocardiography (TTE), and coronary angiography. In all, 22 patients were excluded from the study because the IABP insertion time and reason did not meet the study criteria: 5 patients had the IABP inserted before the percutaneous coronary intervention (PCI), and 17 congestive heart failure (CHF) patients had the IABP inserted for other reasons during their hospitalization. The study was approved by the local medical ethics committee.

A clinical history of risk factors, such as age, sex, hypertension (HT), diabetes mellitus (DM), smoking, hyperlipidemia, peripheral artery disease, or chronic lung and kidney disease was determined from the ICCU electronic database. Echocardiographic findings were also obtained from the same database. TTE was performed using a Vivid 3 system (GE Vingmed Ultrasound AS, Horten, Norway) in the first 48 hours in the coronary care unit and left ventricular ejection fraction (EF) was calculated using Simpson method.^[11] The pulmonary arterial peak systolic pressure was calculated using the simplified Bernoulli equation.

Blood values obtained from venous blood samples at hospital admission were recorded from the medical reports. White blood cell count (WBC), hemoglobin

level, and neutrophil count were measured as part of the automated complete blood count using a Coulter LH 780 Hematology Analyzer (Beckman Coulter, Inc., Brea, CA, USA). Biochemical measurements were performed using Siemens Healthcare Diagnostic Products GmbH kits and calibrators (Marburg, Germany).

The IABP was inserted via the femoral artery without a sheath insertion. The IABP was instituted using 1:1 electrocardiographic triggering and weaning was performed by reduction of the electrocardiographic triggering from 1:1 to 1:2 to 1:3 trigger ratios. The IABP was inserted in all of the patients after PCI, and the decision to use an IABP was left to the discretion and guidance of the supervising cardiologist.

Definitions

HT was defined as systolic pressure ≥ 140 mmHg, diastolic pressure ≥ 90 mmHg, or a history of antihypertensive medication use. DM was defined as use of insulin or antidiabetic agents in the patient's medical history, or a fasting glucose level ≥ 126 mg/dL. Hyperlipidemia was defined as a serum total cholesterol ≥ 240 mg/dL, serum triglyceride ≥ 200 mg/dL, low-density lipoprotein cholesterol ≥ 130 mg/dL, or previously diagnosed hyperlipidemia. Cardiogenic shock was defined as hypotension (systolic blood pressure < 90 mmHg) despite adequate filling status with signs of hypoperfusion despite vasopressor treatment with at least 2 vasopressors.

Statistical analysis

The data analysis was performed using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY, USA) software. The Kolmogorov-Smirnov test was used to test the distribution pattern. Data were presented as mean \pm SD for normally distributed data, and as median (interquartile range) for continuous variables that were not normally distributed. The number of cases and percentages were used for categorical data. The mean differences between groups were compared using the Student's t-test. The Mann-Whitney U test was applied for comparisons of the data that were not normally distributed. Categorical data were analyzed with Fisher's exact test when 1 or more cells had an expected frequency of 5 or less. Otherwise, Pearson's chi-square test was applied. Multiple logistic regression analysis using the backward logistical regression method was applied to de-

termine the best predictor(s) that affect mortality after adjustment for all possible confounding factors. Any variable that had a univariable test p value < 0.25 was accepted as a candidate for a multivariable model, along with all variables of known clinical importance. Odds ratios (ORs) and 95% confidence intervals (CIs) for each independent variable were also calculated. A p value less than 0.05 was considered statistically significant.

RESULTS

A total of 142 (66.2% male) acute coronary syndrome patients who had an IABP inserted in the ICCU were evaluated in this study. The patients were analyzed with respect to in-hospital mortality (Table 1). The mean age of the patients was 63.0 \pm 9.7 years. Among these patients, 67 had HT (47.1%), 73 had DM (51.4%), and 87 (61.3%) were smokers. In addition, 54 of the patients had previously been diagnosed with hyperlipidemia (38.0%). Furthermore, 27 patients (19.0%) had MI, 7 patients had a cerebrovascular accident (4.9%), 1 patient had aortic valve replacement (1.2%), 19 patients had coronary artery bypass graft surgery (13.3%), and 30 patients had PCI history (21.1%). In the group, 60 patients (42.2%) had a CHF diagnosis, 17 had (11.9%) chronic obstructive pulmonary disease, and 55 patients (38.7%) had chronic renal failure (CRF).

All of the patients were under inotropic agent treatment when the IABP was inserted. The patients were all treated with primary PCI before the IABP insertion. Survivors were notably younger than non-survivors ($p < 0.001$). The prevalence of CRF was found to be significantly greater in non-survivors ($p < 0.001$). A TIMI flow score ≤ 2 in a culprit artery after the intervention was also found to be significantly greater in non-survivors ($p < 0.001$). The left ventricle EF was significantly greater in survivors ($p = 0.012$).

Laboratory data of the study groups are provided in Table 2. The serum creatinine, glucose, and lactate levels were notably higher in non-survivors ($p < 0.001$, $p = 0.016$, and $p < 0.001$, respectively). The univariate and multivariate logistic regression predictors of in-hospital mortality are indicated in Table 3 and Table 4. CRF (OR: 2.855; 95% CI: 1.088–7.493; $p = 0.033$), TIMI score post PCI ≤ 2 (OR: 8.163; 95% CI: 2.599–25.634; $p < 0.001$), glucose (OR: 1.014; 95% CI:

Table 1. Comparison of demographic and clinical characteristics of patients according to mortality

	Mortality (-) (n=64)	Mortality (+) (n=78)	<i>p</i>
Age (years)	58.0 (52.0–67.5)	66.0 (58.0–72.0)	<0.001
Female/Male	19 (29.7%)/ 45 (70.3%)	29 (37.2%)/49 (62.8%)	0.348
Hypertension	31 (48.4%)	36 (46.2%)	0.786
Diabetes mellitus	32 (50.0%)	41 (52.6%)	0.761
Smoking	39 (60.9%)	48 (61.5%)	0.942
Hyperlipidemia	23 (35.9%)	31 (39.7%)	0.642
Previous myocardial infarction	16 (25.0%)	11 (14.1%)	0.100
Previous cerebrovascular accident	2 (3.1%)	5 (6.4%)	0.458
Previous aortic valve replacement	0	1 (1.3%)	1.000
Previous coronary artery bypass graft	9 (14.1%)	10 (12.8%)	0.829
Previous percutaneous coronary intervention	13 (20.3%)	17 (21.8%)	0.830
Congestive heart failure	4 (6.2%)	10 (12.8%)	0.191
Chronic obstructive pulmonary disease	9 (14.1%)	8 (10.3%)	0.487
Chronic renal failure	16 (25.0%)	44 (56.4%)	<0.001
Peripheral arterial disease	4 (6.2%)	7 (9.0%)	0.754
Anterior wall myocardial infarction	36 (56.2%)	43 (55.1%)	0.893
Atrial fibrillation	3 (4.7%)	4 (5.1%)	1.000
TIMI flow in culprit before intervention			
TIMI 0	57 (89.1%)	73 (93.6%)	0.335
TIMI 1	7 (10.9%)	5 (6.4%)	0.335
TIMI flow in culprit after intervention			
TIMI ≤2	8 (12.5%)	45 (57.7%)	<0.001
TIMI 3	56 (87.5%)	33 (42.3%)	<0.001
Coronary artery bypass graft	11 (17.2%)	11 (14.1%)	0.613
Intervened vessel			
Left anterior descending artery	35 (54.7%)	45 (57.7%)	0.719
Circumflex artery	6 (9.4%)	3 (3.8%)	0.299
RCA: Right coronary artery	11 (17.2%)	10 (12.8%)	0.466
Multivessel	11 (17.2%)	20 (25.6%)	0.225
IABP usage days	3.0 (2.0–4.0)	3.0 (1.0–5.0)	0.661
Inotropic agents			
Dobutamine infusion	35 (54.7%)	37 (47.4%)	0.390
Dopamine infusion	59 (92.2%)	74 (94.9%)	0.731
Noradrenaline infusion	48 (75.0%)	57 (73.1%)	0.795
Adrenaline infusion	13 (20.3%)	21 (26.9%)	0.358
Central venous pressure	9.0 (6.0–11.5)	9.0 (8.0– 12.0)	0.288
Left ventricular ejection fraction (%)	35.0 (30.0–40.0)	26.5 (20.0–35.0)	0.012
Left ventricular end-diastolic diameter (cm)	5.40 (4.95–5.60)	5.60 (5.10–6.20)	0.060
Left ventricular end-systolic diameter (cm)	4.00 (3.30–4.80)	4.50 (3.90–5.00)	0.003
Tricuspid annular plane systolic excursion (cm)	1.85 (1.55–2.15)	1.80 (1.50–2.20)	0.637
Pulmonary artery systolic pressure (mmHg)	25.0 (20.0–35.0)	30.0 (24.0–38.0)	0.049
Mitral regurgitation ≥+3	7 (10.9%)	17 (21.8%)	0.086
Intra-aortic balloon pump related complications			
Bleeding	12 (18.8%)	16 (20.5%)	0.793
Vascular injury	1 (1.6%)	3 (3.8%)	0.627
Thrombocytopenia	6 (9.4%)	8 (10.3%)	0.861

Continuous variables are presented as mean±standard deviation. Nominal variables are presented as frequency (%). TIMI: Thrombosis in Myocardial Infarction.

Table 2. Comparison of laboratory parameters of patients according to mortality

	Mortality (-) (n=64)	Mortality (+) (n=78)	p
Laboratory variables at admission			
Hematocrit (%)	36.5±6.0	36.7±6.4	0.868
Hemoglobin (g/dL)	12.3±2.0	12.3±2.1	0.837
White blood cell (cells/ μ L)	17.3 (13.7–19.3)	17.5 (12.6–23.2)	0.396
Platelet count (/mm ³)	255 (202–265)	243 (199–291)	0.870
Creatinine (mg/dL)	1.10 (0.86–1.23)	1.59 (1.22–1.95)	<0.001
Blood urea nitrogen (mg/dL)	22.0 (16.0–27.0)	25.5 (18.0–40.0)	0.016
Potassium (mEq/L)	4.15 (3.50–4.50)	4.80 (4.00–5.50)	0.176
Sodium (mEq/L)	136 (134–139)	138 (131–143)	0.380
Aspartate transaminase	221 (51–283)	333 (41–342)	0.034
Alanine transaminase	54 (32–77)	53 (27–135)	0.170
Lactate dehydrogenase	394 (247–929)	641 (389–951)	0.042
International normalized ratio	1.3 (1.1–1.6)	1.4 (1.2–1.9)	0.198
Glucose (mg/dL)	120 (95–135)	136 (93–167)	0.016
C-reactive protein	3.70 (2.75–4.50)	3.80 (3.50–4.50)	0.107
Lactate	2.95 (2.25–4.40)	5.50 (4.20–9.40)	<0.001
Peak values			
Creatinine	1.34 (1.11–2.05)	3.05 (1.91–4.10)	<0.001
Aspartate transaminase	187 (70–442)	475 (166–1475)	0.001
Alanine transaminase	89 (59–155)	142 (98–916)	0.012
Lactate dehydrogenase	905 (583–1479)	1325 (691–1973)	0.076

1.001–1.027; $p=0.035$), lactate (OR: 1.468; 95% CI: 1.191–1.809; $p<0.001$), and EF (OR: 0.927; 95% CI: 0.882–0.975; $p=0.003$) were defined as multivariate predictors of in-hospital mortality.

DISCUSSION

The main findings of our study were as follows: successful PCI is one of the important determinants of survival in patients with an IABP, and EF, CRF, and admission glucose and lactate levels are independent predictors of mortality in patients with an IABP.

An IABP is still one of the most-used methods for mechanical hemodynamic support in the ICCU, although its benefit continues to be debated. It is mostly inserted in patients with MI complicated with cardiogenic shock in addition to conventional medical therapy. Despite mechanical support, the mortality rate of hemodynamically deteriorated patients is still unacceptably high. The in-hospital mortality rate of

patients treated with an IABP varies according to the clinical indication for IABP use. The in-hospital mortality rate for patients treated with an IABP in Taiwan was recently reported to be 13.8%.^[12] It was higher in the United States (20.1%) and Europe (28.7%) between 1997 and 2002.^[13] Our mortality ratio was quite high, 54.9%, which was considered to be the result of strictly selected, critically ill patients. An IABP is most often used in patients with coronary artery disease.^[12,14] The in-hospital mortality rate of patients with acute MI complicated by cardiogenic shock was reported as 47.9% by Babaev et al.,^[15] and as 42% in the Benchmark Counterpulsation Outcomes Registry database.^[16] When compared with other studies, the higher mortality rate in our study might be explained by the inclusion of a larger percentage of Killip class IV acute MI patients who were treated with PCI.

In the literature, there are limited data regarding the parameters that effect mortality in patients with an IABP. Therefore, we sought to compare survivors and

Table 3. Univariate logistic regression analyses between in-hospital mortality and baseline, clinical, angiographic and laboratory data

Univariate analysis	<i>p</i>	OR (95% CI)
Age	<0.001	1.079 (1.038–1.122)
Chronic renal failure	<0.001	3.882 (1.887–7.987)
Previous congestive heart failure	0.200	2.206 (0.658–7.400)
Thrombosis in myocardial infarction ≤ 2 after intervention	<0.001	9.545 (4.014–22.701)
Blood urea nitrogen	0.007	1.031 (1.008–1.054)
Aspartate transaminase	0.188	1.000 (1.000–1.001)
Potassium	0.177	1.491 (0.835–2.660)
C-reactive protein	0.077	1.318 (0.970–1.791)
Glucose	0.009	1.012 (1.003–1.021)
Lactate	<0.001	1.562 (1.290–1.891)
Ejection fraction	<0.001	0.962 (0.931–0.995)
Left ventricular end-diastolic diameter	0.054	1.608 (0.958–2.700)
Left ventricular end-systolic diameter	0.022	1.837 (1.211–2.787)
Pulmonary artery systolic pressure	0.200	1.021 (0.989–1.053)
Mitral regurgitation ≥ 3	0.091	2.269 (0.876–5.876)
Multivessel intervention	0.228	1.661 (0.728–3.790)

OR: Odds ratio; CI: Confidence interval.

Table 4. Multivariate analysis demonstrating independent predictors of mortality

Multivariate analysis	<i>p</i>	OR (95% CI)
Chronic renal failure	0.033	2.855 (1.088–7.493)
Glucose level	0.035	1.014 (1.001–1.027)
Lactate level	<0.001	1.468 (1.191–1.809)
Thrombosis in myocardial infarction ≤ 2 after intervention	<0.001	8.163 (2.599–25.634)
Ejection fraction	0.003	0.927 (0.882–0.975)

OR: Odds ratio; CI: Confidence interval.

non-survivors in order to determine predictive parameters. Between the 2 groups, TIMI score post-PCI of ≤ 2 , EF, CRF, and admission glucose and lactate levels were demonstrated to be statistically higher in non-survivors. Additionally, EF was found to be notably higher in the survivor group. CRF is a well-accepted risk factor for mortality in high-risk patients. CRF was detected as a predictor of in-hospital mortality in patients with acute heart failure.^[17] Baseline impaired renal function was associated with poor prognosis in patients with ST-elevation MI and cardiogenic shock.^[18] Similarly, CRF was revealed to be an independent mortality predictor in patients with an IABP in our study. A TIMI flow score of ≤ 2 in the culprit artery af-

ter intervention was also demonstrated to be a strong predictor of death by De Felice et al.^[19] According to the findings of our study, TIMI flow score may be used as a risk stratification of patients with an IABP. In addition, the admission serum glucose and lactate levels appeared in a new score designed using a step-wise, multivariable regression analysis for patients with cardiogenic shock.^[20] EF has been universally accepted as a cardiac parameter with proven predictive value.^[21]

In our study, bleeding, vascular injury, and thrombocytopenia were the complications related to IABP insertion. They are frequently encountered complications of IABP. Infections, balloon rupture, balloon

entrapment, and cell destruction are other reported complications. Despite the fact that the encountered complications were similar to those described in the literature, major complications were not seen in our study population.^[22] The risk for complications potentially increases with longer duration of IABP use.^[22] No major complication in our study was thought to be secondary to shorter duration of IABP use.

Study limitations

One of the limitations of our study is its retrospective observational design. We had a limited number of patients with an IABP inserted, which prevents the generalizability of our findings. Mortality was found to be extremely high due to the inclusion of Killip class IV acute MI patients treated with PCI.

Conclusion

Our study revealed that an IABP is a poor choice in patients with cardiogenic shock due to acute coronary syndrome and that the mortality rate in these patients was unexpectedly higher than the rates reported in the literature. Renal, echocardiographic, and angiographic parameters can be used as mortality predictors in patients with an IABP. As a result, insertion of an IABP is a choice available to provide mechanical support in selected patients that should be made based on correct timing and clinical indication. Patients who have a higher risk of mortality should be further treated with other mechanical circulatory support devices.

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Keywords: Cardiac care unit; cardiogenic shock; intra-aortic balloon pump; myocardial infarction.

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