



## The Factors Predicting Retroperitoneal Hematoma Following Intra-Aortic Balloon Pump Insertion Site Injury

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### ABSTRACT

**Background:** Retroperitoneal Hematoma (RPH) is one of the most serious complications after Intra-Aortic Balloon Pump (IABP) insertion. Although advances in clinical experience regarding IABP insertion have led to a decrease in vascular complications such as RPH, its rate has remained considerably high.

**Objectives:** This study aimed to evaluate the factors predicting RPH following IABP insertion site injury.

**Methods:** This retrospective cohort study of 2508 patients undergoing off-pump Coronary Artery Bypass Graft (CABG) surgery over 4.5 years allowed the identification and evaluation of all patients with RPH. The patients were divided into with RPH and without RPH groups. RPH prediction was analyzed by multivariate stepwise logistic regression analysis. SPSS, version 22 (SPSS Inc., Chicago, IL) was used for statistical analysis.

**Results:** RPH developed in 16 patients (overall prevalence: 0.63%), with the highest frequency in low ejection fraction patients (3%). Female gender, compartment syndrome, IABP insertion site, preoperative Clopidogrel usage, use of post-operative inotropic drugs, and body surface area were the predictors of RPH in multivariate analysis. Moreover, in-hospital mortality was significantly higher in the patients who had developed RPH compared to those who had not (50% vs. 1.9%,  $P = 0.004$ ).

**Conclusions:** RPH is a serious vascular access site complication of IABP, which has been associated with high morbidity and mortality. The current study findings indicated that such factors as female gender, BSA, IABP insertion site, preoperative Clopidogrel usage, IABP usage, and post-operative inotrope drugs use could predict RPH. Identification of RPH risk factors could in turn prevent this problem.

### 1. Background

Intra-Aortic Balloon Pump (IABP) has been widely accepted as a simple, effective mechanical circulatory assist method for the management of cardiac complications in patients with heart failure (1). However, the rate of complications when using an IABP is considerably high, which is often related to vascular injury (2).

Retroperitoneal Hematoma (RPH) is one of the most serious complications after IABP insertion. RPH may be associated with a common femoral artery or iliac artery puncture after the intervention for IABP insertion (3, 4). Retroperitoneum is a place for a large volume of blood with

few external demonstrations until hypovolemia occurs, leading to delayed detection, increased mortality, and a potentially fatal result (4, 5).

Although advances in clinical experience regarding IABP have resulted in a decrease in vascular complications following IABP insertion like RPH, its rate has remained considerably high. The incidence of RPH has been reported as 0.5% in the recent studies. Thus, it has been referred to as an infrequent but significant complication following IABP insertion (5). Access site complications have also been found to result in higher rates of morbidity, mortality, and hospitalization (6-8).

### 2. Objectives

This study aims to evaluate the factors predicting RPH following IABP insertion site injury.

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### 3. Patients and Methods

#### 3.1. Population

This retrospective study was conducted on 2508 consecutive patients who had undergone Coronary Artery Bypass Graft (CABG) surgery in Imam Ali Hospital affiliated to Kermanshah University of Medical Sciences between October 2013 and December 2019. The data were gathered from the patients' medical records. It should be noted that there was no intervention in the routine medical treatment of the patients in this study. Because of missing records, twenty patients were excluded. The patients were divided into with RPH and without RPH groups. The following variables were collected: age, gender, diabetes, Ejection Fraction (EF), hypercholesterolemia, Body Surface Area (BSA), aspirin intake, preoperative Clopidogrel and heparin usage, emergent surgery, post-operative inotropic drugs use, IABP use, smoking, opium use, peripheral vascular disease, left main coronary artery disease, preoperative creatinine > 1.5 mg/dL, and post-operative compartment syndrome. The patients who had associated heart valve disease were excluded from the study.

#### 3.2. Definition

Renal failure was defined as creatinine > 1.5 mg/dL. Hypertension was defined as systolic arterial pressure > 140 mmHg, diastolic pressure > 90 mmHg, or use of at least one anti-hypertensive medication. Re-exploration was defined as the reopening of the sternum during the first seven days for bleeding or bypass revision. EF was assessed by catheterization or echocardiography. Peripheral Vascular Disease (PVD) was defined as a history of intermittent claudication or Transient Ischemic Attack (TIA), documented stenotic lesion in the carotid artery, renal artery, or iliac artery, or previous vascular surgery.

Preoperative renal insufficiency was determined by serum creatinine > 1.5 mg/dL. Low cardiac output was defined as a need for inotropic support more than five micro/minute or usage of IABP. The insertion site was classified into two zones with regard to the inguinal canal. In zone A, the needle passed 3 cm below or above the inguinal canal. In zone B, the needle passed > 3 cm below the inguinal canal.

#### 3.3. Statistical Analysis

Continuous and discrete variables were presented as means  $\pm$  Standard Deviations (SDs) and percentages, respectively. Student's t-test and Mann-Whitney U test were used to evaluate the significant differences between the study groups. Furthermore, categorical variables were evaluated using chi-square or Fisher's test. To assess the factors predicting RPH, the data were analyzed using multivariate stepwise logistic regression analysis. SPSS, version 22 (SPSS Inc., Chicago, IL) was used for statistical analysis, and  $P < 0.05$  was considered statistically significant.

### 4. Results

#### 4.1. Baseline Demographics and Clinical Characteristics

RPH occurred in sixteen out of the 2528 patients. The patients who had developed RPH were older than those who had not. In addition, RPH occurred more frequently in females (75% of the patients with RPH vs. 61.2% of those without RPH,  $P = 0.003$ ), diabetic patients, those with  $EF \leq 30\%$ , those with  $BSA < 1.8 \text{ m}^2$ , the patients who had received pre-operative heparin, Clopidogrel, post-operative inotrope drugs, and PVD, and those with post-operative compartment syndrome (Table 1). There was no significant difference between the groups with and without RPH regarding the use of opium and aspirin, method of IABP insertion, emergent surgery, hypocholesteremia, and smoking. The incidence

**Table 1.** Preoperative Variables in the Patients with and without Retroperitoneal Hematoma

Variables	Without RPH = 2492	With RPH = 16	P-value
Age (y)	55.3 $\pm$ 8.2	74.8 $\pm$ 3.8	< 0.001
Female gender (%)	61.2% (1525)	75% (12)	0.003
Left main coronary artery disease (%)	10.6% (264)	31.2% (5)	0.025
Ejection fraction $\leq 30\%$	7.6% (189)	25% (4)	< 0.001
Aspirin usage (%)	92.4% (2302)	91.1% (296)	0.419
Post-operative compartment syndrome (%)	0.00% (0)	81.25% (13)	< 0.001
Smoking (%)	13.3% (331)	15.4% (50)	0.339
Emergent surgery (%)	9.4% (234)	18.75% (3)	0.123
Preoperative heparin usage (%)	4.3% (107)	50% (8)	< 0.001
Post-operative inotropic drugs use	11.1 (276)%	100% (100)	0.000
Diabetes (%)	21.8% (543)	37.5% (6)	0.002
Hypercholesterolemia (%)	30.4% (757)	31.25 (5)	0.055
Method of IABP insertion (O/C %)	20% (498)	18.75% (3)	0.589
Opium usage (%)	15.1% (376)	18.75% (3)	0.907
Preoperative Clopidogrel usage	10.3% (256)	31.25 (5%)	0.000
Peripheral vascular disease (%)	5.15% (128)	37.5% (6)	0.000
Preoperative creatinine > 1.5 mg/dL (%)	3.4% (84)	12.5% (2)	< 0.001
IABP insertion site (%) zone A/B	15.2% (11) / 84.8% (64)	81.25% (13) / 18.75% (3)	< 0.001
IABP	3% (75)	100% (16)	< 0.001
Body surface area (m <sup>2</sup> )	1.8 $\pm$ 0.2	1.7 $\pm$ 0.2	0.003
Mortality (%)	1.9%	50%	0.004

Abbreviations: IABP, intra-aortic balloon pump. Data have been presented as mean  $\pm$  SD or number (percentage), RPH: Retroperitoneal Hematoma.

of IABP insertion was 3% (75) in the group with RPH and 100% (16) in the group without RPH.

#### 4.2. Multivariate Predictors of IABP Insertion

The factors predicting postoperative IABP insertion in univariate analysis included female gender, hypercholesterolemia, PVD, and BSA (Table 2). In multivariate logistic regression analysis, the significant variables were female gender, EF < 30%, preoperative heparin usage, diabetes, PVD, and BSA (Table 2).

#### 4.3. Multivariate Predictors of RPH

The factors predicting RPH in univariate analysis included female gender, left main coronary artery

disease, preoperative heparin usage, smoking, post-operative compartment syndrome, emergent surgery, IABP insertion site, diabetes, hypocholesterolemia, opium usage, preoperative Clopidogrel usage, peripheral vascular disease, preoperative creatinine > 1.5 mg/dL, BSA, IABP usage, and post-operative inotropic drugs use. In logistic multivariate analysis, the significant factors associated with RPH were female gender, compartment syndrome, IABP insertion site, preoperative Clopidogrel usage, post-operative inotropic drugs use, and BSA (Table 3).

### 5. Discussion

The prevalence of RPH was 0.63% in the present study, which was the largest experience of RPH reported in the

**Table 2.** The Factors Predicting Intra-Aortic Balloon Pump Insertion by Logistic Regression Analysis

Variables	Univariate			Multivariate		
	OR	95% CI	P	OR	95% CI	P
Age (year)	0.99	0.91 - 1.09	0.960			
Female gender (%)	0.49	0.25 - 0.97	0.040	3.23	0.99 - 6.34	0.001
Left main coronary artery disease (%)	1.06	0.42 - 2.70	0.896			
Ejection fraction ≤ 30%	2.19	1.02 - 4.73	0.046	2.12	0.87 - 5.67	0.003
IABP insertion site (%)	0.80	0.27 - 2.37	0.680			
Smoking (%)	0.28	0.06 - 1.19	0.084			
Emergent surgery (%)	1.32	0.55 - 3.19	0.541			
Preoperative heparin usage (%)	0.30	0.07 - 1.29	0.105	0.26	0.06 - 1.18	0.001
Diabetes (%)	2.21	1.00 - 4.89	0.051	2.24	0.94 - 5.30	0.008
Hypercholesterolemia (%)	2.21	1.08 - 4.53	0.031			
Opium usage (%)	0.50	0.17 - 1.46	0.2.2	0.34	0.05 - 1.11	
Peripheral vascular disease (%)	2.56	0.26 - 25.24	0.003	1.24	0.022 - 6.56	0.004
Preoperative creatinine > 1.5 mg/dL (%)	1.03	0.29 - 3.63	0.960			
Body surface area (m <sup>2</sup> )	0.69	0.09 - 5.31	0.000	2.23	0.012 - 4.32	0.000

Abbreviations: CI, confidence interval; IABP, intra-aortic balloon pump.

**Table 3.** The Factors Predicting Retroperitoneal Hematoma by Logistic Regression Analysis

Variables	Univariate			Multivariable		
	OR	95% CI	P	OR	95% CI	P
Age (year)	0.88	0.84 - 1.11	0.758			
Female gender (%)	3.11	0.12 - 1.11	0.000	2.78	0.101 - 0.34	0.001
Left main coronary artery disease (%)	0.42	0.05 - 3.30	0.410			
Ejection fraction ≤ 30%	2.90	0.81 - 8.80	0.050			
Aspirin usage (%)	1.18	0.22 - 10.20	0.050			
Pre-operative heparin usage (%)	1.16	0.25 - 5.39	0.044			
Smoking (%)	0.41	0.05 - 3.22	0.397			
Intra-abdominal compartment syndrome (%)	4.67	1.55 - 14.13	0.006	3.55	0.97 - 13.02	0.055
Emergent surgery (%)	0.44	0.06 - 3.47	0.033			
IABP insertion site	0.95	0.92 - 0.98	0.002	0.96	0.93 - 0.99	0.021
Diabetes (%)	0.15	0.01 - 2.49	0.404			
Hypercholesterolemia (%)	1.95	0.63 - 6.00	0.245			
Hypertriglyceridemia (%)	0.46	0.10 - 2.09	0.313			
Opium usage (%)	0.41	0.05 - 3.22	0.397			
Preoperative Clopidogrel usage	0.81	0.74 - 0.90	< 0.001	0.85	0.78 - 0.94	0.001
Peripheral vascular disease (%)	2.36	0.12 - 45.87	0.421			
Preoperative creatinine > 1.5 mg/dL (%)	2.09	0.44 - 9.89	0.354			
Body surface area (m <sup>2</sup> )	0.13	0.01 - 2.97	0.022	3.56	0.11 - 6.54	0.041
IABP usage (%)	0.98	0.90 - 1.08	0.001	2.31	0.051 - 7.11	0.002
Post-operative inotropic drugs use	1.02	0.99 - 1.05	0.000	3.132	0.09 - 7.15	0.002

Abbreviations: CI, confidence interval; IABP, intra-aortic balloon pump.

literature. This finding was in line with a previous report of RPH (0.6%) (9, 10).

In the present study, several risk factors emerged as independent predictors of RPH, including female gender, IABP insertion site, preoperative Clopidogrel usage, BSA, IABP usage, and post-operative inotrope drugs use. Farouque et al. (3) conducted a study and indicated that the incidence of RPH was 0.712% in 3508 consecutive patients undergoing Percutaneous Coronary Intervention (PCI). They demonstrated that female gender, low BSA, and higher femoral artery punctures were the independent predictors of RPH. Moreover, they revealed no significant association between RPH and the size of the arterial sheath, use of glycoprotein IIb/IIIa inhibitors, and deployment of a vascular closure device (3).

In the current research, IABP insertion site was another predictor of RPH events [Odds Ratio (OR): 0.96; 95% Confidence Interval (CI): 0.93 - 0.99]. Most studies have reported that bleeding was related to the insertion site and could vary from mild to severe (11). In the present study, IABP insertion site was a risk factor for RPH, which was consistent with the previous reports (9, 12).

Similar to the previous investigations, the present study findings indicated that female gender was an independent risk factor for RPH. Females have estrogen that affects arterial structures (5), a smaller common femoral artery dimension, and different arterial mechanical properties (13) that may increase the risk of bleeding. In the previous reports, female gender was identified as an independent predictor of RPH (13). This suggested that additional attention should be paid to the risk of postoperative RPH in female patients. Previous reports also hypothesized that different arterial mechanical properties, smaller common femoral artery dimensions, and estrogen-related arterial structures in females might increase the need for multiple arterial punctures and the risk of bleeding (11, 14, 15).

In line with the previous reports (3), BSA was another independent predictor for RPH in the present study. This might be partly due to its association with a smaller femoral artery diameter, leading to arterial access problems (3). Clopidogrel usage before the operation was another predictor of RPH in the current investigation. Previous studies have also shown Clopidogrel therapy as a risk factor for RPH (16, 17).

In the present research, the mortality rate was 50% in the patients who had RPH, which was significantly higher compared to those who did not have RPH. It has been demonstrated that RPH was an important risk factor for death and could lead to severe morbidity and mortality (15, 18, 19), making prompt diagnosis and treatment essential. A previous report also indicated that the mortality rate was 4% (10). It seems that the most important complication for RPH is related to the vessel site for catheter insertion, which can increase the risk of RPH. If treated inappropriately, it can result in high morbidity and mortality.

### 5.1. Limitations

This was a retrospective study and the accuracy of the data depended on the recorded history. However, it represented a large number of cases.

### 5.2. Strengths

All data were collected from a single hospital as a referral center in the western region of the country. In addition, all surgeries were performed by a single surgeon using the off-pump technique.

### 5.3. Conclusions

RPH is a serious vascular access site complication of IABP and has been associated with high morbidity and mortality rates. The present study findings indicated that female gender, BSA, IABP insertion site, preoperative Clopidogrel usage, IABP usage, and post-operative inotrope drugs use were the risk factors of RPH.

### 5.4. Ethical Approval

IR.KUMS.REC.1395.466

### 5.5. Informed Consent

A retrospective analysis of the 2528 consecutive patients undergoing CABG at Imam Ali Hospital of Kermanshah University of Medical Sciences between October 2013 and December 2019 was undertaken. Data was gathered by medical records and there was no intervention in routine medical treatment of the patients in this study.

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### Authors' Contribution

F.S. carried out the literature research, participated in the sequence alignment, and drafted the manuscript, A.A. helped collect the data, M.R. wrote the manuscript, R.H. analyzed the data, A.H. developed the manuscript and advised on valuable amendments. The authors read and approved the final manuscript.

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The authors have no financial interests related to the material in the manuscript.

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