

In which conditions should we insert an intra-aortic balloon pump? In the operating room or intensive care unit?

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ABSTRACT

Objectives: In this study, we aimed to evaluate complications of intra-aortic balloon pump catheters inserted percutaneously in the operating room versus in the intensive care unit setting.

Patients and methods: Between January 2013 and January 2016, a total of 71 patients (54 males, 17 females; mean age 63.0 years, range, 41 to 84 years) who underwent percutaneous intra-aortic balloon pump insertion in the operating room or in the intensive care unit were retrospectively reviewed. The patients were divided into two groups as Group 1 (n=48) consisting of the patients with intra-aortic balloon pump inserted in the operating room and Group 2 (n=23) consisting of those who underwent intra-aortic balloon pump in the intensive care unit. Both groups were compared in terms of pre- and post-procedural data and the effects of intra-aortic balloon pump insertion performed in the intensive care unit and operating room settings on reproductive pathology results of the catheters were assessed.

Results: The mean pre- and post-procedural platelet counts were significantly higher in Group 2 than Group 1. After the procedure, the incidence of growth only was higher in the cultures collected from the tips of the catheters inserted in the intensive care unit.

Conclusion: Insertion of intra-aortic balloon pump catheters in the operating room is more secure than the catheters inserted in the intensive care unit in terms of catheter infections. Therefore, in patients who are scheduled for intra-aortic balloon pump support in the intensive care unit setting, this procedure should be considered to be performed under operating room conditions, if the mobility of the patient is ensured.

Keywords: Complication, infection, intra-aortic balloon pump.

Although cardiogenic shock following cardiac surgery is less than 1%, it is associated with a high rate of mortality.^[1] Low blood outflow and ischemia in organs can be prevented with mechanical support where dramatic responses to pharmacological therapy cannot be obtained during this critical period.^[2]

Intra-aortic balloon pump (IABP) support is the first invasive treatment option in cases of post-cardiotomy syndrome in which low outflow syndrome or cardiogenic shock predominate. These pumps are inserted percutaneously or surgically during the pre-, intra-, or postoperative period in the intensive care unit (ICU) or operating room (OR) setting. The rate of complication may vary depending on the surgically or percutaneously insertion of IABP in OR or ICU setting.

In the present study, we aimed to evaluate complications of IABP catheters inserted percutaneously in the OR versus in the ICU setting.

PATIENTS AND METHODS

Between January 2013 and January 2016, a total of 71 patients (54 males, 17 females; mean age 63.0 years, range, 41 to 84 years) who underwent percutaneous IABP insertion in the OR or in the ICU were retrospectively reviewed. Data were retrieved from the hospital registry system. The indication of IABP insertion was post-cardiotomy cardiogenic shock. Exclusion criteria were as follows: patients with contamination suspicion while taking catheter tip samples for culture. A written informed consent was obtained from each patient. The study protocol was

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approved by the Katip Çelebi University Faculty of Medicine Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The study population consisted of patients under medical follow-up in the ICU as candidates for open heart surgery and undergoing open heart surgery. The patients were divided into two groups as Group 1 (n=48) consisting of the patients with IABP inserted in the OR and Group 2 (n=23) consisting of those who underwent IABP in the ICU. Data including baseline demographic and clinical characteristics of the patients, and intra- and postoperative findings were recorded. Both groups were compared in terms of complications and

microbiological growth pathologies of the tips of the balloon catheters.

The patients were diagnosed with systemic inflammatory response syndrome (SIRS) in the postoperative period based on the 2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference criteria. Accordingly, the presence of at least two of the following data was considered as SIRS: body temperature $>38^{\circ}\text{C}$ or $<36^{\circ}\text{C}$, pulse $>90/\text{min}$, respiratory rate $>20/\text{min}$ or partial pressure of carbon dioxide $<32\text{ mmHg}$, and leukocyte count $>12,000\ \mu\text{L}^{-1}$ or $<4,000\ \mu\text{L}^{-1}$.^[4]

The IABP catheters were removed under aseptic conditions in patients who did not require clinical IABP support and the catheter tips were sent to the

Table 1
Pre- and intraoperative data of study population

	Group 1 (n=48)			Median	Group 2 (n=23)			<i>p</i>	
	n	%	Mean±SD		n	%	Mean±SD		
Age (year)			63.1±9.8	62.5			64.4±8.2	65.0	0.588*
Gender									0.138**
Male	39	81.3			15	65.2			
Female	9	18.8			8	34.8			
Diabetes mellitus	20	41.7			10	43.5			0.885**
COPD	12	25			13	43.7			0.009**
Smoking	34	70.8			16	69.6			0.913**
Hypertension	38	79.2			19	82.6			0.733**
Cerebrovascular events	3	6.3			1	4.3			0.745**
Peripheral arterial disease	16	33.3			8	34.8			0.904**
Ejection fraction			47.1±12.5	50			46.5±13.5	45	0.920†
EuroSCORE			5.5±2.2	6			5.7±2.7	5.5	0.867†
Body surface area			1.8±0.2	1.8			1.79±0.2	1.8	0.197†
Preoperative Hb (g/dL)			12.9±2.2	12.9			11.8±1.9	11.4	0.062†
Postoperative Hb (g/dL)			9.6±1.6	9.3			9.4±1.6	9.1	0.540†
Preoperative WBC ($\times 10^3$)			7.7±2.9	7.8			8.7±4.0	8.5	0.217†
Postoperative WBC ($\times 10^3$) (K/uL)			15.8±5.7	16.0			18.8±5.6	19.6	0.049†
Pre-IABP PLT ($\times 10^3$) (K/uL)			235±74.3	227.5			251.6±86.2	249.0	0.531†
Post-IABP PLT ($\times 10^3$) (K/uL)			101.3±62.9	92.0			135.4±85.1	115.0	0.045†
Preoperative creatinine (mg/dL)			1.0±0.3	0.9			1.3±0.7	1.0	0.366†
Postoperative creatinine (mg/dL)			1.8±0.9	1.6			2.2±1.2	2.1	0.353†
Cross-clamping time (min.)			117.9±66.3	105.0			100.2±37.1	94.5	0.446†
CPB time (min.)			59.6±31.0	51.0			53.0±29.6	55.0	0.758†

SD: Standard deviation; * T test; ** Chi square (Fischer test); † Mann-Whitney U test; COPD: Chronic obstructive pulmonary disease; Hb: Hemoglobin; WBC: White blood cell; PLT: Platelet; IABP: Intra-aortic balloon pump; CPB: Cardiopulmonary bypass.

microbiology laboratory to compare microbiological growth pathologies in sterile conditions. The same procedure was also applied to the IABP catheters of patients who died. Culture results were obtained under monitoring.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean \pm standard deviation (SD), median (min-max), or number and frequency. The distribution of the variables was measured using the Kolmogorov-Smirnov test. The independent sample t-test and Mann-Whitney U test were used in the analysis of quantitative independent data. The chi-square test was used to analyze qualitative independent data, and the Fisher's test was used, when the chi-square test conditions were not met. A *p* value of <0.05 was considered statistically significant.

RESULTS

There was no significant difference in the baseline demographic and clinical characteristics including age, gender, body surface area, ejection fraction, rate of smoking, incidence of hypertension, diabetes mellitus, cerebrovascular events, and peripheral artery disease between the groups ($p>0.05$). In Group 2, however, the incidence of chronic obstructive pulmonary disease (COPD) was significantly higher than Group 1 ($p<0.05$) (Table 1). Of the patients included in the study, 19 (39.6%) in Group 1 and 13 (56.5%) in

Group 2 died, indicating no statistically significant difference between the groups (Table 1).

According to the results of laboratory tests, the mean platelet count and leukocyte count were significantly higher after the termination of IABP in the patients who underwent IABP insertion in the ICU than the patients who received IABP in the OR ($p<0.05$). No significant difference was found in the other laboratory test results between Group 1 and Group 2 (Table 1).

There was no significant difference in the intraoperative data between the groups (Table 1). However, after the termination of IABP, the culture positivity rate was found to be significantly higher in the patients who underwent insertion in the ICU compared to those who received IABP in the OR ($p<0.05$) (Table 2). Although there was a significant difference in the culture results, the positivity of SIRS, the use of antibiotics and high body temperature ($>38^{\circ}\text{C}$) did not differ between the groups. There was also no significant difference in the duration of mechanical ventilation and ICU stay between Group 1 and 2.

DISCUSSION

Intra-aortic balloon pump is the most commonly used device which is easy to access, easy to implement, inexpensive, and still the most widely used device which increases myocardial supply and demand balance, by improving myocardial performance.^[5] However, several complications may be seen due

Table 2
Postoperative data after the termination of IABP

	Group 1 (n=48)			Group 2 (n=23)			<i>p</i>
	n	%	Mean \pm SD	n	%	Mean \pm SD	
Culture outcome (+)	11	22.9		11	47.8		0.034
Patients using antibiotics	29	60.4		11	47.8		0.317
Temperature $>38^{\circ}\text{C}$	29	60.4		13	56.5		0.755
SIRS (+)	32	66.7		19	82.6		0.162
IABP complication (+)	4	8.3		1	4.3		1.000
Duration of extubation (h)			32.9 \pm 44.7			29.9 \pm 19.8	0.192
Duration of intensive care (h)			12.4 \pm 12.9			9.8 \pm 9.7	0.416
Mortality	19	39.6		13	56.5		0.179

IABP: Intra-aortic balloon pump; SD: Standard deviation; SIRS: Systemic inflammatory response syndrome.

to its widespread use. These complications include vascular complications, balloon-related complications, and infections. Vascular complications include lower extremity ischemia, peripheral thrombosis and embolism, vasospasm which may result from local vascular damage during insertion of the catheter, hematoma, pseudoaneurysm, arteriovenous fistula, major vessel injury with mechanical effect of the catheter, aortic dissection, spinal cord ischemia, and malperfusion of visceral organs. Balloon-related complications include dislocation or migration of the balloon, balloon rupture which may lead to gas embolization, anemia, and thrombocytopenia resulting from trauma to erythrocytes and platelets with mechanical effect. In addition, IABP catheter-related local wound infections and systemic infections among the rare complications which should be kept in mind.^[6,8-12] In the literature, IABP complications are similar to those reported in our study population. Among the patients with IABP inserted in the OR, critical leg ischemia was observed in two patients and retroperitoneal hematoma due to vascular trauma in one patient. In addition, local wound infection was observed in one patient in each group, and was taken under control with antibiotherapy without any need for surgical debridement.

In the vast majority of patients with IABP inserted, laboratory investigations yield abnormalities.^[13,14] Inflation and deflation in the balloon catheter with the mechanical effect cause trauma to platelets and erythrocytes. This situation manifests as thrombocytopenia and anemia. Studies conducted by Bream-Rouwenhorst et al.^[14] and McCabe et al.^[13] demonstrated that the most common side effect of IABP was thrombocytopenia, which was reported in 47 to 82% of patients. Similar results were also obtained in our study. Thrombocytopenia was observed in 85.7% of the patients 24 hours after the procedure. Furthermore, when the patients who received IABP in the OR and those who received IABP in the ICU were compared, the relative decrease in the platelet counts was statistically significantly higher in the in patients undergoing IABP in the OR setting ($p < 0.005$). This difference, undoubtedly, is largely due to the exposure of cardiopulmonary bypass during open heart surgery. In addition, nine patients (18.7%) in Group 1 underwent mediastinal re-exploration due to bleeding revision and eight (88.9%) of these patients had thrombocytopenia. Therefore, it should be kept in mind that thrombocytopenia may cause redo surgery

and an increased amount of blood transfusion due to postoperative bleeding in patients undergoing open heart surgery and it may further complicate the clinical picture of patient.

When used at an early stage and timely in an appropriate location and in a proper way, IABP assists both the patient and the surgical team. Therefore, mortality and morbidities, length of stay in the ICU, duration of mechanical ventilation, and location and timing of IABP application have been repeatedly investigated and the discrepancies among the studies have been a subject of many clinical studies. In a study, Torchiana et al.^[15] classified the location of IABP insertion as medical intensive care, surgical intensive care, and OR and included these locations in the multivariate analysis for mortality predictors. The authors reported that early decision for IABP insertion and performing percutaneous IABP insertion in the preoperative ICU setting reduced mortality. In parallel with this finding, Christenson et al.^[16] and Metz et al.^[17] also found more promising results in terms of mortality, duration of mechanical ventilation, and length of stay in the ICU in patients with IABP inserted preoperatively in the ICU. In our study, the mean length of stay in the ICU in the patients with IABP inserted was found to be 7.5 days in Group 1 and 7 days in Group 2, indicating no statistically significant difference. Also, there was no statistically significant difference in the total duration of mechanical ventilation between the groups. The rate of mortality was found to be 39.6% in Group 1 and 56.5% in Group 2.

Nosocomial infections seen in patients followed with IABP are rarely associated with the IABP catheter alone. Since patients subjected to IABP support usually have more than one monitoring lines in addition to the balloon pump, it should be kept in mind that the presence of these lines is an additional factor in the frequency of fever and bacteremia. Review of the literature reveals the increased incidence of nosocomial infections in patients with IABP insertion.^[10,11] In the studies by Beckman et al.^[12] and McCabe et al.^[13] evaluating the complications of IABP, the incidence of local wound site infection was found to be 2.2 to 5%. In a study by Pawar et al.^[18] including 136 patients with IABPs inserted, the most common systemic infection resulted from the respiratory system and this was attributed to the increased incidence of atelectasis and superinfection in patients who were unable to be mobilized while under the support of IABP. In another

study by Goldberg et al.^[19] with 101 patients comparing percutaneous and surgical techniques, the rates of local (2%) and systemic (4%) infections were found to be higher in patients undergoing the surgical method. In many studies conducted, it has been demonstrated that the frequency of infections associated with IABP was directly proportional to the duration of IABP therapy and it has been suggested that the IABP catheter as well as all invasive lines should be removed as soon as possible to avoid this complication. In our study, local wound infection was observed in the femoral region where the IABP catheter was applied in one patient in each group, and this was controlled with proper antibiotherapy without any need for surgical debridement. Although no significant difference was found between the groups in terms of fever and the use of antibiotics, pathogens were isolated in the catheter tips sent to the laboratory in 11 patients (22.9%) from Group 1 and 11 patients (47.8%) from Group 2, which was found to be statistically significant ($p=0.034$). It is clear that the main reason for this result is the sterile environment provided by the operative conditions in the patients where the insertion was performed in the OR. Although IABP catheters were inserted in the ICU conditions under aseptic conditions, the results indicate that these efforts are not as reliable as those of the OR conditions.

The limitations of this study are its retrospective design and small sample size. On the other hand, the fact that makes our study valuable is the microbiological assessment of pathological growth in the samples collected from the catheter tips after termination of IABP therapy which was performed using the same technique in the ICU or in the OR after the termination of IABP treatment. To the best of our knowledge, this is the first study in this regard in the literature.

In conclusion, in our study, complications of intra-aortic balloon pump application, which has been increasingly used due to the ease of use and relatively low cost in low cardiac output syndrome, were examined in great detail. However, it is noteworthy that significant differences were found in the outcomes of catheter cultures, although strict asepsis was followed in our intensive care unit and the experience of the team which performed the insertion procedures and undertook care of the patients. Therefore, to reduce infective complications of intra-aortic balloon pump, all intra-aortic balloon pump catheters can be considered to be inserted in the operating rooms

setting. Nonetheless, further large-scale, prospective, randomized-controlled studies are warranted to gain a better understanding on this topic.

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