Vascular complications of intra-aortic balloon pump usage in coronary bypass surgery: 18 years of experience

Pages with reference to book, From 31 To 35

Abdulkadir Ercan, Orcun Gurbuz (Department of Cardiovascular Surgery, Balikesir University, School of Medicine, Balikesir, Turkey.)
Arzu Ercan (Department of Cardiovascular Surgery, Sevgi Hospital, Balikesir, Turkey.)
Oktay Tuydes, Murat Bicer, Davit Saba (Department of Cardiovascular Surgery, Uludag University, School of Medicine, Bursa, Turkey.)
Hayati Ozkan (Department of Cardiovascular Surgery, Acibadem Hospital, Bursa, Turkey.)

Abstract

Objective: To evaluate the vascular complication incidence related to intra-aortic balloon pump usage during coronary bypass surgery and possible risk factors.
Methods: The retrospective study was conducted at Uludog University Hospital, Turkey, and comprised 147 cases in which intra-aortic balloon pump was used during coronary artery bypass surgery between January 1994 and December 2011. Data was examined in terms of age, gender, diabetes mellitus, hypertension, smoking, peripheral vascular disease, pre-operative serum creatinine, history of congestive heart failure, left ventricular ejection fraction, previous infarction and cardiac functional capacity. Time, indication, treatment duration, technique of insertion and complications were recorded about the balloon insertion. Patients in whom peripheral vascular complication developed were evaluated with pulse examination, Doppler ultrasound and angiography. Logistic regression analyses were carried out with the purpose of determining the relation between pre-operative clinical variables and vascular complications and mortality.
Results: Of the total, 105 (71%) were males and 42 (28%) were females. The overall mean age was 62.4±10.1 years. Besides, 16 (41%) cases had diabetes mellitus and 30 (20%) had peripheral artery disease. The mean Euroscore was 7.6±4.8. Intra-aortic balloon pump was inserted in 16 (10.8%) due to pre-operative high risk and in 75 (51%) cases due to hypotension being non-responsive to inotropes. Balloon catheter was placed with percutaneous technique in 141 (96%) cases and sheath wasn't used in 44 (29%). The balloon stayed for 2.9±2.1 days on average. Balloon rupture developed in 1 (0.6%) case. Mortality resulted in 58 (39%) cases. Euroscore ($p=0.012$), staying in hospital ($p=0.005$), low ejection fraction ($p=0.018$), hypertension existence ($p=0.003$) in multivariate logistic regression analyses were found significant in terms of affecting mortality. Duration of therapy ($p<0.001$), existence of sheath ($p=0.002$), and existence of peripheral vascular disease ($p<0.001$) were found significant as factors affecting the development of vascular complication.
Conclusion: Intra-aortic balloon pump provides mechanical circulation assistance during coronary artery surgery, but peripheral vascular system should be well evaluated in order to avoid vascular complications and the balloon catheter should be placed without the sheath if necessary. The duration of the therapy is a risk factor for the development of vascular complication.
Keywords: Intra-aortic balloon pumping, Coronary artery bypass surgery, Vascular system injuries.
(JPMA 64: 28; 2014).

Introduction

Intra-aortic balloon pump (IABP) is widely used in cardiovascular surgery with the purpose of circulation support. Its clinical usage was first stated in 1968 in a patient with cardiogenic shock based on acute myocardial infarction (MI).[1] In addition to its usage in low cardiac output treatment after

cardiac surgery, its pre-operative usage in risky patients is increasing.[2,3] It is used in patients with high risk for serious cardiovascular conditions, haemodynamic stabilisation after acute MI or cardiogenic shock, angioplasty or coronary bypass surgery.[4-6] In addition to its common usage via percutaneous method, it is also inserted with open surgery method. The incidence of vascular complication about IABP usage has been stated to be of 2, 6-11, 7%.[7,8]
In recent years, complications have arisen despite developments in IABP catheter technology and pre-operation precise examination of vascular structure. In this study, vascular complications related IABP usage was retrospectively analysed.

Patients and Methods

The retrospective study involved 147 cases in which IABP was used during coronary artery bypass surgery between January 1994 and December 2011 in Cardiovascular Surgery Clinic of Uludag University, Faculty of Medicine, Training and Research Hospital, Turkey. Information for age, gender, diabetes mellitus, hypertension, smoking, peripheral vascular disease, pre-operative serum creatinine, congestive heart failure (CHF) history, left ventricular ejection fraction, previous infarction, cardiac functional capacity belonging to patients were collected. Time, indication, treatment duration, technique of insertion and complications were recorded about the balloon insertion. Patients in whom peripheral vascular complication has been developed were evaluated with pulse examination, Doppler ultrasound (US) and angiography. Urgent surgery was used for cases that had to undergo surgery within 24 hours after angiography or referral, while emergency surgery was used for cases that underwent the surgery within a few hours. Intermittent claudication history and low peripheral pulses or presenting vascular pathology with Doppler US/angiography were used in defining peripheral vascular disease. Vascular complications were analysed under two groups as major and minor. While major aortic dissection or perforation, extremity ischaemia requiring thrombectomy/repair/bypass surgery/faciotomy/ amputation were defined as vascular complications; infection in the region where balloon was implanted, bleeding in the input of balloon and ischaemia which improved with the removal of balloon were defined as minor vascular complications. Vascular complications associated with the balloon were recorded.
IABP catheter was inserted by the percutaneous Seldinger method. Open technique was used in cases in which it was not possible for the catheter to be implanted with the percutaneous method; 8.0-9F and 35-40ml volumes were used as catheter. Balloon volumes were activated between 34ml and 40ml according to the patient's body mass index (BMI). The place of catheter was controlled with chest X-ray. All patients were heparinised after IABP implantation. The dose of heparin was monitored with activated clotting time (ACT) and held between 150 and 200 sec. Before the removal of the balloon, heparin was discontinued about half-an-hour earlier. Pulse was checked regularly. If the pulse couldn't be taken and an ischaemia existed, Doppler US was performed. If any obstruction was seen in the femoral artery with Doppler US, the balloon was removed, and inserted on the other side if required. If there was still occlusion or thrombus in Doppler US after the balloon's removal, the patient was taken for surgery.
In, terms of data analyses, frequencies, percentages, mean values and standard deviations were calculated. Categorical variables were also stated as a percentage. P value was considered significant below 0.05. Logistic regression analyses were used to establish the relation between peri-operative clinical variables and the development of vascular complications and mortality.

Results

Overall, 105 (71%) patients were males and 42 (28%) were female. The mean age was 62.4±10.1 years.

Of the total, 61 (41%) had diabetes mellitus and 30 (20%) had peripheral artery disease. The mean Euroscore was 7.6±4.8. While 16 (10%) patients underwent emergency surgery, 67 (45%) had undergone urgent surgery, and routine operation was carried out in 64 (43%). Besides, 81 (55%) had myocardial infarction before the procedure and 51 (34%) had low EF (Table-1).

Table-1: Patient characteristics.

Patient Characteristics	Number (n = 147)	Percentage (%)
Age	62.4 ±10.1	
Male	105	71.4
Female	42	28.5
Diabetes Mellitus	61	41.4
Chronic Renal Failure	13	8.8
Hypertension	80	54.4
Smoking	87	59.1
Peripheral Arterial Disease	30	20.4
Left Main Coronary	38	25.8
Ejection Fraction %		
< % 30	51	34.6
% 30 - 50	56	38.1
> % 50	40	27.2
Reoperation	9	6.1
Type of Operation		
Emergency	16	10.8
Urgent	67	45.5
Routine	64	43.5
Previous Myocardial Infarction	81	55.1
Chronic Obstructive Pulmonary Disease		23
15.6		
NYHA		
Class II	19	12.9
Class III	51	34.6
Class IV	77	52.3
Staying in Balloon (day)	2.9±2.1	
Hospitalisation (day)	11.1±8.4	
Euroscore	7.6±4.8	

NYHA: New York Heart Association.

Off-pump coronary artery bypass grafting (Off-pump CABG) was performed in 43 (29.2%) patients; CABG with conversion to cardiopulmonary bypass (CPB) after starting off-pump was carried out in 37 (25%) patients; CABG with CPB was performed in 58 (39.4%) and CABG + left ventricular aneurysmectomy was performed in 9 (6.1%) (Table-2).

Table-2: Operative procedures. indications. and insertion times.

Parameter	Number (n=147)	Percentage (%)
Operation		
Off-Pump CABG	43	29.2
Off-Pump CABG → Conversion to CPB	37	25.1
CABG with CPB	58	39.4
CABG + Left ventricular aneurysmectomy	9	6.1
Indication		
Because of preoperative high risk	16	10.6
After anaesthesia induction	7	4.7
Difficulty weaning off CPB	43	29.2
Hypotension with no response to inotrope. PHT	75	51
Arrhythmia	5	3.4
Protamine reaction	1	0.6
Implantation time		
Preoperative	23	15.6
Intraoperative	93	63.2
Postoperative	31	21

CABG: Coronary artery bypass grafting. CPB: Cardiopulmonary bypass. PHT: Pulmonary hypertension.

Balloon was inserted in 16 (10.6%) patients because of pre-operative high risk; in 7 (4.7%) after anaesthesia induction; in 43 (29.2%) because of difficulty weaning off CPB; in 75 (51%) because of hypotension with no response to inotrope and pulmonary hypertension; and in 5 (3.4%) because of arrhythmia. Balloon was inserted in 93 (63.2%) patients intraoperatively. Only 6 (4%) balloon catheters were inserted with open method, while others were inserted with percutaneous method. Forty four

(30%) balloons were inserted without sheath; sheath was used in 103 (70%) balloons. While the shortest duration for inserted IABP was 3 hours, the longest duration was 10 days. Balloons remained in place for 2.9±2.1 days on average.

Complications about the balloon were seen in 18 (12%) patients. Among them, lower extremity ischaemia developed in 12 (66.6%); thromboembolectomy in 3 (16.66%) and femoral artery repair in 2 (11.11%) were carried out as primary mode. Femoro-femoral bypass was performed in 1 (5.55%) patient. Saphena interposition was required between the main femoral artery and superficial femoral artery. Faciotomy was done in 1 (5.5%) patient. Ischaemia decreased in 4 cases after the removal of IABP. Haematoma was seen in 3 (2%) and IABP tear was seen in 1 (0.6%) patient. Balloon rupture occurred in 1 (0.6%) patient. One catheter was inserted via the femoral vein.

Mortality occurred in 58 (39%) patients. In univariate analyses, hypertension (p<0.001; OR: 2.7; 95% CI: 1.57-4.93); low level of EF (p<0.001; OR: 11.22; 95% CI: 4.43-28.50); Euroscore (p<0.001; OR: 1.22; 95% CI: 1.12-1.33) and vascular complication development (p=0.042; OR: 2.7; 95% CI: 1.03-7.03) were found to be significant factors affecting mortality. Euroscore (p=0.012; OR: 1.13; 95% CI: 1.02-1.25); hospitalization time (p=0.005; OR: 0.94; 95% CI: 0.91-0.98); low EF (p=0.018; OR: 3.8; 95% CI: 1.25-12.0); hypertension (HT) (p=0.003; OR: 2.63; 95% CI: 1.38-5.02) were independent risk factor for mortality in multivariate logistic regression analysis (Table-3).

Table-3: Multivariate logistic regression analysis of the predictive variables for vascular complications and mortality.

Independent Variables for Vascular complications for OR	B	p	95% CI OR
Staying in Balloon (day)	0.556	0	1.744	1.41- 2.14
PVD	2.573	0	13.104	3.93- 43.61
Existence of sheath	2.42	0.002	11.248	2.43- 51.85
Constant	-6.971	0	0.001	
Independent Variables for Mortality				
Eurscore	0.128	0.012	1.137	1.02- 1.25
Hospitalization time (day)	-0.053	0.005	0.948	0.91- 0.98
EF < 30%	1.359	0.018	3.892	1.25- 12.03
HT	0.97	0.003	2.637	1.38- 5.02
Constant	0.453	0.594	1.573	

EF: Ejection Fraction. HT: Hypertension. PVD: Peripheral Vascular Disease. OR: Odds Ratio. CI: Confidence Interval.

Factors affecting the development of vascular complication included Euroscore (p=0.017; OR: 1.084; 95% CI: 1.014-1.158); duration for balloon in place (p<0.001; OR: 1.64; 95% CI: 1.37-1.97);

hospitalisation time (p<0.006; OR: 1.05; 95% CI: 1.01-1.09); and existence of peripheral vascular disease (p<0.001; OR: 5.64; 95% CI: 2.38-13.37). Duration for balloon in place (p<0.001; OR: 1.74; 95% CI: 1.41-2.14); existence of sheath (p<0.002; OR: 11.24; 95% CI: 2.43- 51.85) and existence of peripheral vascular disease (p<0.001; OR: 13.10; 95% CI: 3.93- 43.61) were found to be independent risk factors in multivariate logistic regression analysis.

Discussion

IABP is mechanical support device used for temporary ventricular support in heart failure treatment. When the patient profile is analysed, patients in high-risk group, especially males, are generally seen. The current study covering data of 18 years found low EF, New York Heart Assocaition (NYHA) Class IV functional capacity, previous MI, HT and male gender were prominent. In this group of patients, reduction of ventricular afterload, enhancement of subendocardial perfusion and improvement of diastolic coronary perfusion were the main effects of IABP usage. As a result, an improvement in haemodynamic and left ventricular functions was observed.[9]

In IABP-inserted patients, hospital mortality was reported to be between 5.6 and 52.6 % in literature.[6-8] In our study, while hypertension, low level of EF, Euroscore and vascular complication development were found to be significant for the factors affecting mortality in univariate analyses; Euroscore, hospitalisation time low EF, and HT were independent risk factors for mortality in multivariate logistic regression analysis. Mortality occurred in 39% of the study patients.

Vascular complications regarding IABP usage in our patients seemd like extremity ischaemia due to thromboembolism or injury in artery, infection, haematoma due to bleeding and insertion to femoral vein by mistake, and occurred in 10% cases. In addition, perforation, dissection, bleeding, leakage in balloon and amputation have been cited as complications in literature.[7,8] The incidence of vascular complication was stated between 2.6 and 18.1% in literature.[6-8] Mortality directly related to IABP didn't occur in our patients, but catheter-related aortic dissection/perforation and septic gangrene were reported.[6]

In our study, vascular complications occurred in 10% patients. This rate was 27% in group with peripheral vascular disease. Risk factors for vascular complications have earlier been stated as female gender, age, obesity, diabetus mellitus, HT, smoking, peripheral vascular disease and IABP treatment duration.[10-14] In analysis of the factors affecting the development of vascular complication, Euroscore, duration of balloon in place, hospitalisation time, and the existence of peripheral vascular disease were found significant in univariate analysis. Duration of balloon in place, the existence of sheath, and the existence of peripheral vascular disease were found significant in multivariate logistic regression analysis. Maherwal et al. studied vascular complications in 911 cases with inserted IABP and stated the vascular complication rate as 11.7%.[7] It also determined age, three vascular disorders, unstable angina pectoris (USAP), left ventricular aneurysm, sheath usage as independent risk factors.[7] Benchmark stated in the study that mortality directly related to IABP in 16,909 patients at 203 centres between 1996 and 2000 was 0.05%, IABP-related morbidity (major vascular complication) was 2.6%.8 Female gender, advanced age, peripheral artery disease were found as independent risk factors for major complications.[8]

IABP treatment in patients with perioperative high risk was used in patients with low ventricle function, re-operations, left main coronary artery stenosis and unstable patients.[15-18] Dietl et al. retrospectively stated that mortality in patients with low EF and in whom IABP was used was 2.7%, but this rate was 11.9% for the ones in whom IABP wasn't used.[15] In another study, while mortality was found to be 13.6% in pre-operative IABP usage, it was 35.7% in postoperatively inserted patients.[16]

Holmann et al. thought that pre-operative IABP usage was beneficial, but it wasn't so advantageous concerning intra and pre-operative usage survival.[17] In our study, 16 patients had pre-operative high risk. There were 7 cases who had to be resuscitated and taken to surgery. Mortality occurred in 5 patients in this group.

Some authors preferred balloon catheter insertion with open technique in order to decrease the vascular complication rate. The method which is more advantageous than implantation with percutaneous method was used in 6 cases in our study. Percutaneous technique was successful in all other cases. They stated that sheath usage was a risk factor during IABP insertion.[19] In our study, sheath was used in 103 cases and sheath usage was stated as a risk factor. Maherval et al stated that ischaemia decreased in 13 cases among 67 patients with balloon in whom extremity ischaemia developed after sheath removal.[7]

In the current study, duration of balloon being in place was found as an independent risk factor for vascular complication. Manord et al. stated the risk for development of vascular complication in long-term IABP treatment as 32%.[20] Average duration for balloon was 2, 32 days. Balloons remained in place for 2.9±2.1 days on average in our study.

Limitation of the study was its retrospective design. Besides, it was conducted at a single cardiac surgery unit with limited number of cases. A multi-centre study, with a larger cohort of patients is recommended.

Conclusion

Precise vascular examination before balloon implantation is very important and the existence of peripheral artery disease, which is a risk factor for complication, can be detected, and sheathless catheter implantation in such cases may decrease vascular complications. The duration of IABP therapy is a risk factor for development of vascular complications. When extremity ischaemia develops, only removal of balloon catheter is enough in some cases. However, direct arterial surgery may be sometimes required in order to prevent extremity loss.

References

1. Kantrowitz A, Tjonneland S, Freed P, Phillips S, Butner A, Sherman J. Initial clinical experience with intra-aortic balloon pumping in cardiogenic shock. JAMA 1968; 203: 113-8.
2. Babatasi G, Massatti M, Bruno PG, Hamon M, LePage O, Morello R, et al. Pre-operative balloon counterpulsion and off-pump cardiac surgery for high risk patients. Cardiovascular Surg 2003; 11: 145-8.
3. Gong Q, Miao JX, Zhao Y, Jia Z, Chen LY, Gao Q, et al. Beneficial effect of preventative intra-aortic balloon pumping in high risk patients undergoing first time coronary artery bypass grafting - a single centre experience. Artificial Organs 2009; 33: 587-92.
4. Dyub AM, Whitlock RP, Abouzahr LL, Cina CS. Preoperative intra-aortic balloon pump in patients undergoing coronary bypass surgery: a systematic review and meta-analysis. Clin Rev 2008; 23: 79-86.
5. Naunheim KS, Swartz MT, Pennigton DG, Fiore AC, McBride LR, Peigh PS, et al. Intraaortic balloon pumping in patients requiring cardiac operations; risk analysis and long-term follow-up. J Thorac Cardiovasc Surg 1992; 104: 1654-61.
6. Arafa EE, Pedersen TH, Svennevig JL, Fosse E, Geiran OR. Intraaortic balloon pump in open heart operations: 10-year follow-up with risk analysis. Ann Thorac Surg 1998; 65: 741-7.
7. Meharwal ZS, Trehan N. Vascular complications of intraaortic balloon insertion in patients undergoing coronary revascularization: analysis of 911 cases. Eur J Cardiothorac Surg 2002; 21: 741-7.

8. Ferguson III JJ, Cohen M, Freedman RJ, Stone GW, Miller MF, Joseph DL, et al. The current practice of intra-aortic balloon counter pulsation: results from the Benchmark Registry. J Am Coll Cardiol 2001; 38: 1456-62.
9. Maccioli GA, Lucas WJ, Norfleet EA. The intra-aortic balloon pump: a review. J Cardiothorac Anesth 1988; 2: 356-73.
10. Funk M, Gleason J, Foell D. Lower limb ischemia related to use of the intraaortic balloon pump. Heart Lung 1989; 18: 542-52.
11. Makhoul RG, Cole CW, McCann RL. Vascular complications of intra-aortic balloon pump: an analysis of 436 patients. Am Surg 1993; 59: 564-8.
12. Gol MK, Bayazit M, Emir M, Tasdemir O, Bayazit K. Vascular complications related to percutaneous insertion of intra-aortic balloon pumps. Ann Thorac Surg 1994; 58: 1476-80.
13. Dietl CA, Berkheimer MD, Woods EL, Gilbert CL, Pharr WF, Benoit CH. Efficacy and cost-effectiveness of preoperative IABP in patients with ejection fraction of 0.25 or less. Ann Thorac Surg 1996; 62: 401-8.
14. Christenson JT, Badel P, Simonet F, Schmuziger M. Preoperative intra-aortic balloon pump enhances cardiac performance and improves the outcome of redo CABG. Ann Thorac Surg 1997; 64: 1237-44.
15. Holman WL, Li Q, Kiefe CI, McGiffin DC, Peterson ED, Allman RM, et al. Prophylactic value of preincision intraaortic balloon pump: analysis of a statewide experience. J Thorac Cardiovasc Surg 2000;120: 1112-9.
16. Kang N, Edwards M, Larbalestier R. Preoperative intra-aortic balloon pumps in high-risk patients undergoing open heart surgery. Ann Thorac Surg 2001; 72: 54-7.
17. Barnett MG, Swartz MT, Peterson GJ, Naunheim KS, Pennington DG, Vaca KJ, et al. Vascular complications from intra-aortic balloons: risk analysis. J Vasc Surg 1994; 19: 81-7.
18. Cohen M, Dawson MS, Kopistansky C, McBride R. Sex and other predictors of intra-aortic balloon counter pulsation related complications: prospective study of 1119 consecutive patients. Am Heart J 2000; 139: 282-7.
19. Erdogan HB, Goksedef D, Erentug V, Polat A, Bozbuga N, Mansuroglu D, et al. In which patients should sheathless IABP be used? An analysis of vascular complications in 1211 cases. J Card Surg 2006; 21: 342-6.
20. Manord JD, Garrard CL, Mehra MR, Sternbergh WC 3rd, Ballinger B, Ventura HO, et al Implications for the vascular surgeon with prolonged (3 to 89 days) intraaortic balloon pump counter pulsation. J Vasc Surg 1997; 26: 511-5.