

Factors influencing vascular complications of Intra-aortic balloon pump

Shahyad Salehi, MD. Mohammad Sadegh Pour Abbasi, MD* .Nader Givtaj MD.
Ramin Baghaei MD. Bardia Nemati, MD .Rahman Ghafari MD.

Abstract

Background: We evaluated the vascular complications of Intra-aortic balloon pump and risk factors associated with the development of these complications in patients undergoing myocardial revascularization

Methods: 103 consecutive patients with Intra-aortic balloon pump support were evaluated. Univariate and multivariate analyses were performed to identify risk factors for the development of vascular complications.

Results: Seven (7%) patients developed major and 8 (8%) patients developed minor vascular complications. Ischaemia of the limb, requiring thromboembolectomy, developed in 2 (3%) patients. Mean age of the patients was 59 ± 2 years and 41% of the patients were female. Vascular complications (leg ischemia) were not affected by age. The overall mortality was 44%. Multiple logistic regression analysis revealed duration of intra-aortic balloon pump support, emergency of operation and diabetes as independent risk factors. The duration of intra-aortic balloon pump therapy ranged from 9 hours to 7 days (mean 2 days) and **it had a direct linear relation with occurrence of limb ischemia so that the risk was about 16% of patients per 24h ($p = 0.055$)**. prevalence of limb ischemia proved to be higher in diabetic patients ($p = 0.04$). The emergency of operation had clear impact on leg ischemia in patients with intra-aortic balloon pump ($p < 0.02$).

Conclusion: We found no instances of limb ischemia, either minor or major, during the first 24 hours of intra-aortic balloon pump placement, and very importantly, a linear increase in this risk thereafter. Beside other preventive measures to reduce this complication (e.g. . sheathless technique,

smaller catheters, anticoagulation) earlier removal or placement at a different site, optimally before 36 hours after insertion seem prudent specially in high risk groups of patients such as diabetics, those with Body Surface Area (BSA) < 1.65 m², evidences of Peripheral Vascular Disease (PVD) and emergent cases.

Key words: Intra-aortic balloon pump

- Vascular complication
- Coronary artery bypass graft

Background:

The intraaortic balloon pump is the mechanical circulatory assist device inserted most commonly for perioperative cardiac failure(1,2). Provision of mechanical circulatory support through augmentation of the arterial diastolic pressure first was recorded as early as 1953(3). The first experimental results using inflatable latex balloon inserted into the descending thoracic aorta through the femoral artery for the purpose of counterpulsation was reported in 1962 by Mouloupoulos and associates (4).

Although Intra-aortic balloon pump is a well-accepted and widely used mechanical circulatory support, yet the most important limitation in the use of an intra-aortic balloon pumping is the risk of vascular complications(1,5,6,7,8,9). We evaluated the vascular complications of intra-aortic balloon pump and risk factors associated with the development of these complications in patients undergoing myocardial revascularization.

Methods:

103 consecutive patients with intra-aortic balloon pump up to year 2006 were evaluated. Univariate and multivariate analyses were performed to identify risk factors for the development of vascular



complications. Analyses were mainly performed through SPSS 16; charts were produced using Microsoft Office EXCEL 2007.

Results:

Mean age of the patients was 59 ± 2 years and 41% of the patients were female. Limb ischemia (defined as reduced arterial flow as manifested by diminished pulse) occurred in 8 (8%) of cases, and major limb ischemia (absence of pulse, loss of sensation, pallor or reduced limb temperature) was reported in Seven (7%) patients. limb Ischemia, requiring thromboembolectomy, developed in 2 (2%) patients which is similar to other reports(1).. No amputation was reported. Vascular complications (limb ischemia) were not affected by age. The overall mortality was 44% which is close to other reports (53.2%: Gol et al (10)). Multiple logistic regression analysis revealed duration of intra-aortic balloon pump support, emergency of operation and diabetes as independent risk factors. The duration of intra-aortic balloon pump therapy ranged from 9 hours to 7 days (mean 2 days) and it had a direct linear relation with occurrence of limb ischemia so that the risk was about 16% of patients per 24h (percent of patients with normal limb pulse was: 100, 79, 73 and 60% at 24, 36, 60 and 72h after intra-aortic balloon pump insertion respectively figure 1; $p = 0.055$). Prevalence of limb ischemia proved to be higher in diabetic patients ($p = 0.04$). The emergency of operation had clear impact on limb ischemia in patients with intra-aortic balloon pump in a manner that all patients with emergent operation had some sort of limb ischemia (12%, 30% and 100% for elective, urgent and emergent operation respectively; $p < 0.02$ figure 2). Also the absence normal limb pulse was strongly suggestive of mortality so severely so that only 23% of such patients survived (in contrast to about 91% of patients with normal pulses; $p < 0.001$ figure 3) very interestingly this later results have also been reported by MK Gol et al (65.7% versus 50.8% respectively; $p = 0.018$). Vascular complications (leg ischemia) were not affected by age (figure 4).

Discussion:

The intra-aortic balloon pump is the most widely used of all circulatory assist devices today (11). The hemodynamic effects of intra-aortic balloon pumps are well known. The most important limitation in the use of an intra-aortic balloon pumping is the risk of vascular complications (12).

Intra-aortic balloon pump complications include major limb ischemia, severe bleeding, balloon leak, death directly due to intra-aortic balloon pump insertion or failure (13) and thrombocytopenia (14). The incidence of major balloon-related complications was 12% in our study. This was very higher than reported 2.8% in well known multicentre study (15) involving 911 cases at 243 institutions over 18 countries, perhaps because that we used intra-aortic balloon pump in more ill patients. Table 1 summarizes in-hospital balloon-related complications of intra-aortic balloon pump in this large registry. This later study established that female gender, PVD (Peripheral Vascular Disease), BSA (<1.65 m²) and age (over 75 years) remain the four prominent, independent predictors of a serious intra-aortic balloon pump complication. These four high risk groups may become a focus of efforts to improve clinical outcomes and to reduce intra-aortic balloon pump complications. In our study female gender was associated with poorer outcome though not conclusively significant ($p = 0.15$).

Perhaps the most prominent result of our study is a time-dependent linear increase in occurrence of limb ischemia ($y = -0.007x + 1.125$; y: percent of patients without ischemia and x: time in hours, figure 1). This, if confirmed by other investigations, may signify earliest removal of intra-aortic balloon pump as patient condition permits.

Conclusion:

No doubt that intra-aortic balloon pump when indicated and properly handled is very effective cardiac support and has low complications. Even these complications may be lessened by measures such as sheathless technique, smaller catheters, anticoagulation and as it was shown by this study, earlier removal or placement at a different site optimally before 36 hours after insertion specially in high risk groups of patients such as diabetics, those with BSA < 1.65 m², evidences of PVD and emergent cases.

	Surgery	
	CABG (n = 9,179)	Non-CABG (n = 1,086)
In-hospital mortality (%)	16.8	37.8
Mortality—balloon in place (%)	9.2	19.8
intra-aortic balloon pump-related mortality*(%)	0.0	0.0
Amputation ³	0.1	0.1
Major limb ischemia (%)	1.2	1.0
Any limb ischemia (%)	3.5	2.5
Severe access site bleeding (%)	0.7	0.7
Any access site bleeding (%)	1.7	1.3
Balloon leak (%)	1.1	0.5
Composite outcomes		
Major intra-aortic balloon pump complication (%)	3.0	2.9
Any intra-aortic balloon pump complication(%)	7.1	6.0
Any unsuccessful intra-aortic balloon pump(%)	2.5	2.4

1. Death as direct consequence of intra-aortic balloon pump
 2. All major limb ischemia
 3. Loss of pulse or sensation, abnormal limb temperature or pallor, requiring surgical intervention.
 4. Balloon leak, severe bleeding, major limb ischemia or death as a direct consequence of intra-aortic balloon pump therapy.
 5. Any access site bleeding, any limb ischemia, balloon leak, poor inflation, poor augmentation, insertion difficulty or death as direct result of intra-aortic balloon pump therapy.
 6. Balloon leak, poor inflation, poor augmentation or insertion difficulty.

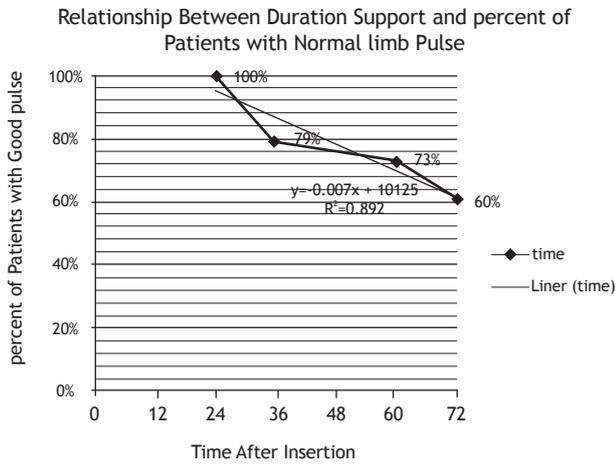


Figure 1: linear regression between duration of intra-aortic balloon pump support and occurrence of limb ischemia

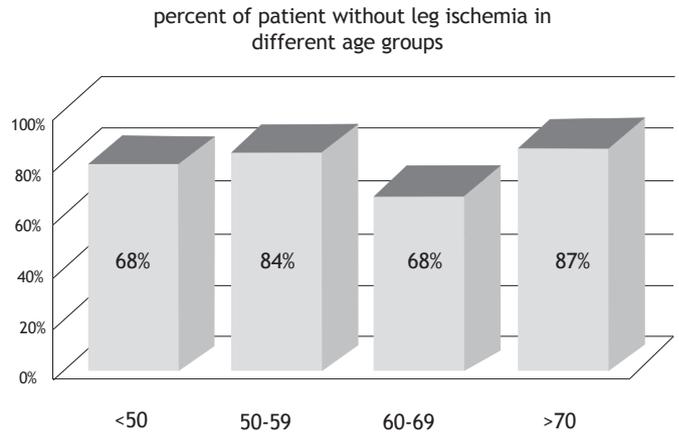


Figure 4: prevalence of limb ischemia in different age groups

percent of patient with good limb pulse

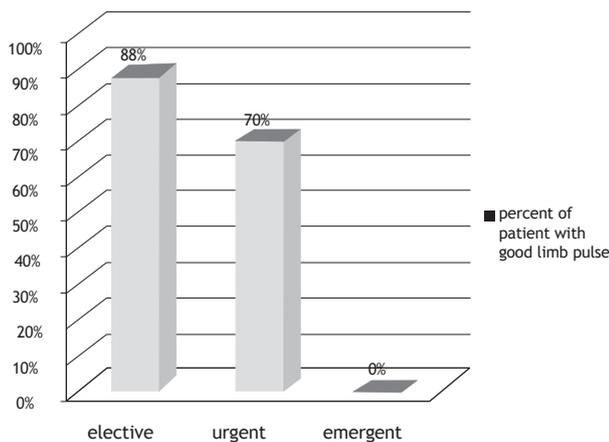


Figure 2: limb ischemia as a function of emergency of the operation

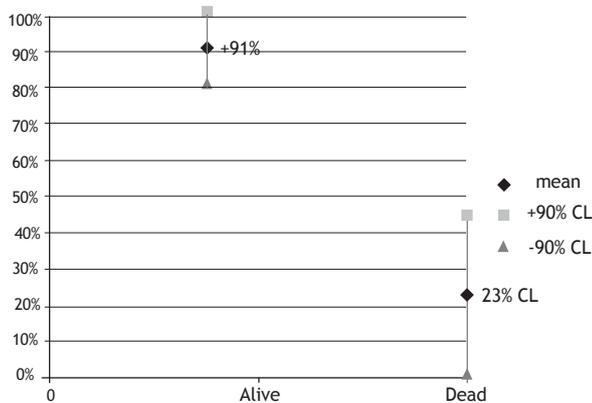


Figure 3: The absence of normal pulse of the subjected limb as a strong indicator for mortality

References:

1. Osma E, Arafa, Thore H, Pedersen, Jan L, Svemevig, Erik Fosse, Odd R, Geiran. Vascular complications of the intraaortic balloon pump in patients undergoing open heart operations: 15 years experience. *The Annals of Thoracic surgery*, March 199; 67: 645-651
2. K.S Naunheim, M.T Swartz, D.G. Pennington et al., Intraaortic balloon pumping in patients requiring cardiac operations. Risk analysis and longterm follow-up. *J thorac cardiovascular Surg* 1992; 104: 1654-1661.
3. A. Kantrowitz and Kantrowitz, Experimental augmentation of coronary flow by retardation of the arterial pressure pulse. *Surgery* 1953; 34: 678-687.
4. S.D Mouloupoulos, S. Topaz and W.J. Kollff, Diastolic balloon pumping (with carbon dioxide) in the aorta; a mechanical assistance to the failing circulation. *Am heart J* 1962; 63: 669-975.
5. D.J. Mackenzie, W.H. Wagner, D.A. Kwber et al., Vascular complications of the intraaortic balloon pump. *Am J Surg*; 1992; 164: 517-521.
6. M Funk, J. gleason and D. Foell, lower limb ischemia related to use of the intraaortic balloon pump. *Heart Lung* 1989; 18: 542-552
7. J.m. Isner, S.r. Cohen, R. Virmani, w. Lawrinson and W.C. Roberts, Complications of the intraaortic balloon counterpulsation device: Clinical and morphologic observation in 45 necropsy patients. *Am J Cardiol*; 1980; 45: 260-268.
8. M.G. Barnett, M.T. Swartz, G.J. Peterson et al. Vascular complications from intraaortic balloons: risk analysis. *J vasc Surg*; 1994; 19: 81-89.
9. T. Busch, h. Sirbu, D. Zenker and H. Dalichau, Vascular complications related to intraaortic balloon counterpulsation: an analysis of ten years experience. *Thorac cardiovasc Surg*. 1997; 45: 55-59.
10. Gol MK, Bayazit M, Emir M, Tasmemir O and Bayazit K. Vascular complications related to percutaneous insertion of intraaortic balloon pumps. *Cardiovascular Surgery Department, Turkiye Yuksek Ihtisas Hospital, Ankara. The Annals of Thoracic Surgery*, Vol 58, 1476-1480, 1994.
11. Mahaffey KW, Kruse KR, Ohman EM. Perspectives on the use of intra-aortic balloon counterpulsation in the 1990s. In: Topol EJ, editor. *Textbook of Interventional Cardiology. Update 21*. Philadelphia, PA: WB Saunders, 1996; 303-21
12. Menon P, Totaro P, Youhana A, Argano V. Reduced vascular complication after intra-aortic balloon pump insertion using smaller sized catheter and sheathless technique. *Cardiac Surgery and Cardiology Department, Regional Cardiac Center, Morrilton Hospital, SA6 6NL,*



Swansea, UK

13. Ferguson JJ, Cohen M, Freedman RJ, Stone GW, Miller MF, Joseph DL and Ohman EM. The current practice of intra-aortic balloon counterpulsation: results from the Benchmark Registry. *J Am Coll Cardiol*, 2001; 38:1456-1462

14. Vonderheide RH, Thadhani R, Kuter DJ: Association of thrombocytopenia with the use of intra-aortic balloon pumps. *Am J Med* 1998; 105:27

15. Meharwal ZS, Trehan Vascular complications of intra-aortic balloon insertion in patients undergoing coronary revascularization: analysis of 911 cases. Department of Cardiovascular Surgery, Escorts Heart Institute and Research Centre, Okhla Road, New Delhi 110 025, India. *Eur J Cardiothorac Surg* 2002;21:741-747. © 2002 Elsevier Science NL