EARLY VASCULAR COMPLICATIONS OF INTRAAORTIC BALLOON COUNTERPULSATION IN PATIENTS UNDERGOING OPEN HEART SURGERY

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Background and Objectives: The use of IABP is helpful for haemodynamic stability of patients with low cardiac output and compromised left ventricular function in patients who undergo coronary artery bypass grafting. This procedure is also associated with some vascular complications due to the insertion of IABP. The objective of this research was to study the vascular complications in patients with IABP counterpulsation. We observed the clinical outcome of these patients with special reference to post IABP complications in our research. **Methods:** One hundred and six consecutive patients were included in this study from August 2005 to February 2007. Mean age of patients was 58.08±1.814 years. Seventy nine patients (74.5%) were male and 29 (25.5%) were females. Out of these 106 patients, 101 were operated for CABG, one for angina due to aortic stenosis, two patients had ischemic mitral regurgitation and one patient had post infarct VSD. In 102 (96.2%) patients IABP was inserted percutaneously, one patient received transthoracic and in three patients IABP was inserted with open technique. Thirteen (12.3%) patients received IABP with sheath and 93 (87.7%) received IABP without sheath. **Results**: Ten patients (9.4%) out of 106 developed vascular complications due to insertion of IABP. Seven patients (6.6%) had the major complications and 3 (2.8%) patients developed minor vascular complications. Mortality due to vascular complications in 106 patients was 8.49% with $p<0.005$. **Conclusion:** IABP has remarkable beneficial effects in patients with haemodynamic instability due to myocardial ischemia and low cardiac output syndrome. At the same time IABP is related to significant morbidity and mortality related to vascular complications due to its insertion which include limb ischemia, limb loss and even mortality.

Keywords: CABG, IABP, Vascular Complications.

INTRODUCTION

The concept of intraaortic balloon pump counterpulsation (IABP), which forms the basis for pumping, was conceived by Harken[1] in 1958, suggested that a balloon placed over a catheter located in thoracic aorta could produce diastolic augmentation. Placement of the balloon in descending aorta distal to the subclavian artery provides optimal effectiveness. The balloon is introduced in the aorta by means of retrograde passage from a surgical or percutaneous arteriotomy in the femoral artery.[2]

The principle of counterpulsation is the synchronous inflation and deflation of balloon by inert gas (Helium) during the cardiac cycle. The inflation during diastole improves filling of the coronary blood stream and the deflation of balloon at the beginning of systole decreases the intraaortic pressure and reduces afterload for better performance of the left ventricle.[3]

The indications for the use of intraaortic balloon are the patients with low cardiac output and ischemic myocardial changes before and after the open-heart surgery to optimize cardiac output and stabilize cardiac ischemia.[4] Early initiation of intraaortic balloon support results in better haemodynamic profile, reduced mortality, reduced ICU (Intensive care unit) stay in patients with low cardiac output syndrome after coronary artery bypass grafting as compared to pure pharmacologic support or late addition of mechanical support.[5] This method is accompanied by considerably high rate of vascular complications.[6,7] There are different factors that can affect the occurrence of these complications like gender, age, body surface, accompanying diseases (hypertension, diabetes, peripheral vascular disease) the method, duration and timing of insertion.[8,9] In our study we observed the vascular complications and identified the risk factors. The rationale of our study is that with proper understanding of the vascular complications and risk factors leading to these complications, we can identify and prevent these complications in already critically ill patients.

MATERIALS AND METHODS

This prospective randomized study was conducted at Cardiac Surgery Department, Punjab Institute of Cardiology Lahore, from August 2005 to February 2007 in 106 patients during open-heart surgery. All consecutive patients who underwent coronary artery bypass grafting (CABG) and received IABP during this period were included in this study. Data from these patients were collected from patients themselves and their files. Technique used for insertion of IABP was percutaneous, transaortic and by open method. The size of balloon was between 7–8 Fr and was calculated according to body surface area. The balloon volume was

constant at 40 cc. All the patients were monitored in intensive care unit and were regularly examined for vascular complications. Vascular complications of IABP were classified as major and minor. Major complications included vascular injury and limb ischemia that were treated with thromboembolectomy, vascular repair or fasciotomy. Minor complications included limb ischemia that were relieved by removal of IABP without further surgical intervention. Patients were on continuous heparin infusion and APTT (activated partial thromboplatin time) was kept twice the normal to avoid thrombo-embolism. Peripheral pulses of both limbs were monitored and peripheral pulses chart was maintained on hourly basis. Patients who developed vascular complications were shifted to operation theatre for embolectomy or surgical intervention.

Recorded demographic factors and clinical parameters included age, sex, body surface area, hypercholesterolemia, smoking, diabetes mellitus, hypertension, family history of cardiac disease, presence of peripheral vascular disease (defined as claudication and pulse deficit on physical examination) and IABP related variables such as type and volume of balloon, diameter of balloon catheter, technique of balloon insertion and duration of use.

The data was analyzed using SPSS 15.0 (Statistical Package for Social Sciences), Mean±SD are given for normally distributed metric variables and Median±IQR are given for non-normally distributed metric variables. Frequencies and percentages are given for non-metric variables.

Independent sample *t*-test was applied to observe group mean differences and Mann-Whitney U test was applied to observe median differences. Fisher Exact test was applied to observe associations between qualitative variables. A *p*-value of <0.05 was considered statistically significant.

RESULTS

One hundred and six consecutive patients received IABP counterpulsation out of 1700 CABG patients operated from August 2005 to February 2007. Mean age of patients was 58.08±1.814 years. Out of these 106 patients 79 (74.5 %) were male and 29 (25.5 %) were female.

The risk factors distribution of coronary and peripheral arterial disease in these patients were as follows: Out of 106 patients 43 (40.6%) were hypertensive, 49 (45.3%) were diabetic, 38 (35.8%) had the family history of coronary artery disease, 40 (37.7 %) were hyperlipedemic, 48 (45.3%) patients were smoker, 26 (24.5%) patients were obese, 9 (8.5%) had the peripheral vascular disease (Table-1).

Table-1: Patient related vascular complications and risk factors distribution (n=10)

Complication	Yes (%)	No (%)	*p*-value
Hypertension	7(70)	3 (30)	0.073
Diabetes Mellitus	8 (80)	2 (20)	0.007*
Family History	5 (50)	5 (50)	-
Hyperlipidemia	5 (50)	5 (50)	-
Smoking	6 (60)	4 (40)	0.371
Obesity	4 (40)	6 (60)	0.371
PVD	6 (60)	4 (40)	0.371

*Significant at 5% level of significance

These risk factors were among the 106 patients for the development of ischemic and coronary artery disease leading to coronary artery bypass grafting.

The age range of the patients who developed vascular complications is 50–70 years with a mean of 59.30±6.48 years. Similarly height range was between 185 to 125 cm with a mean of 170.70±8.23. Both these variables were not significant for vascular complications to develop. Size of IABP range between 7–8 Fr with a median value of 7.50±1.0, weight of patient varied between 93 to 60 Kg with a median value of 76.50±6.9, duration of IABP range between 2–10 days with median value 13.0±1.2 days, LVEF range between 65–30% with median value of 30.0±8.1% and number of grafts during CABG was 2–5 with median value 3.0±0.9. These variables did not add any significance to vascular complications (Table-2a and 2b).

Table-2a: IABP related risk factors causing vascular complications

Vascular Complications (n=10)			
	Yes (Mean± SD)	No (Mean± SD)	*p*-value
Age	59.30±6.48	55.97±8.98	0.257
Height	170.70±8.23	167.38±9.69	0.298

Table-2b: IABP related risk factors causing vascular complications

	Yes (Median±IQR*)	No (Median±IQR*)	*p*-value
Size of IABP	7.50±1.0	7.39±1.10	0.422
Weight of patient	76.50±6.9	76.5±10.0	0.970
Duration	13.0±1.2	4.0±2.0	0.136
LVEF**	30.0±8.1	30.0±9.2	0.741
No. of Grafts	3.0±0.9	3.0±1.25	0.693

*Interquartile Range, **Left ventricular ejection fraction

Intraaortic balloon pump was inserted due to the following indications: In 101 patients (95.3%) it was due to haemodynamic instability and ongoing ischemia pre, per and postoperatively. One (0.9%) had angina due to severely stenotic aortic valve. One patient (0.9%) had CABG with double valve replacement and developed low cardiac output due to LV dysfunction. Two patients (1.9%) had preoperative ischemic MR and one (0.9%) had the post infarct VSD leading to pulmonary oedema and low cardiac output. IABP was used preoperatively in

these patients for initial haemodynamic stabilization while proceeding for open-heart surgery (Table-3).

Table-3: Indications for the use of Intra-aortic Balloon Pump Counter pulsation

	n	%
Aortic Stenosis	1	0.9
CABG with Low cardiac out put	101	95.3
CABG + DVR	1	0.9
Ischemic MR	2	1.9
Post Infarct VSD	1	0.9
Total	**106**	**100%**

IABP was inserted pre, per and post operatively with or without sheath Timing for insertion of IABP in these patients was related to ischemic changes and haemodynamic compromise due to underlying pathology. Three patients (2.83%) received IABP preoperatively due to ST changes and unstable angina, 74 (69.81%) received IABP peroperatively after completion of grafting due to LV dysfunction, 29 patients (27.35%) received IABP postoperatively after coronary artery bypass grafting in ICU due to ischemic and haemodynamic compromise leading to low cardiac output syndrome (Table-4).

Table-4: Timing and insertion technique used for IABP*

Timing of insertion	**No.**	**%**
Pre- operative	3	2.83
Per- operative	74	69.81
Post- operative	29	27.35
Total	106	100%
Technique of insertion		
Open	3	2.8
Percutaneous	102	96.2
Transaortic	1	0.9
Total	106	100%
Method of insertion		
With Sheath	13	12.3
Sheath less	93	87.7
Total	**106**	**100**

*IABP- Intra-aortic Balloon Pump

Technique used for insertion was open in 3 patients (2.8%), percutaneous insertion was done in 102 (96.2%) patients and one patient (0.9%) had transthoracic insertion of IABP.

Out of these 106 patients, 13 patients (12.3%) received IABP with sheath and 93 (87.7%) patients sheath less IABP catheter insertion (Table-4).

Ten patients (9.4%) out of 106 patients developed vascular complications due insertion of IABP. Seven patients (6.6%) had the major complications and 3 (2.8%) patients developed minor vascular complications. Leg ischemia due to IABP was present in 8 patients (7.5%), one patient (0.9%) developed leg ischemia with compartment syndrome, and one patient (0.9%) developed groin haematoma needing wound exploration (Table-5).

Out of 106 patients who underwent open-heart surgery and received IABP counter pulsation therapy, 10 (9.4%) developed post IABP complications. Interventions for these complications were done on clinical basis. 3 (2.8%) patients required embolectomy, 3 (2.8%) patients were managed conservatively, 1 (0.9%) required fasciotomy and embolectomy of the affected limb, 2 (1.9%) required femoral artery repair after embolectomy. In 1 (0.9%) patient groin exploration was done due to haematoma formation at the site of insertion (Table-6).

Table-5: Major and minor limb ischemia complications distribution

	No.	%
Left leg ischemia	5	4.7
Left leg ischemia & compartment syndrome	1	0.9
Groin Haematoma	1	0.9
Right leg ischemia	3	2.8

Table-6: Interventions done after the establishment of vascular complications

	No.	**%**
Embolectomy	3	2.8
Embolectomy & Fasciotomy	1	0.9
Embolectomy & Femoral artery Repair	2	1.9
Conservative	3	2.8
Groin exploration	1	0.9

DISCUSSION

The use of IABP in haemodynamically compromised patients has significant role in improving the cardiac output. The most benefited patients are those with unstable angina, patients with perioperative LVF or hypotension refractory to inotropic support, patients with difficulty to wean from cardiopulmonary bypass and post operative patients with persistent ischemia and haemodynamic instability. IABP improves cardiac output, significantly decreases oxygen demand and with diastolic augmentation increases coronary flow and myocardial oxygen supply. This phenomenon improves supply to demand ratio and cardiac output.[12]

All these effects are also associated with some complications, especially vascular. The major complications of IABP including aortic dissection or perforation, limb ischemia, haemorrhage and Infection at balloon site relieved after surgical intervention along with minor complications like limb ischemia relieved by removal of IABP are matter of great concern. Pseudoaneurysm, neurologic foot drop are late complications.[13]

The causative factors for complications are: Obturation of the lumen (balloon sheath), Thrombosis of vessel and embolisation in peripheral vessel, Injury of the vessel wall i.e. laceration of vessel and arterial dissection.[12]

Many authors and investigators reported their work and experience with the use of IABP counterpulsation technique. Complications occurred among those patients who had some risk factors.[12] In a study conducted by Fergusson,[3] 68.8% were male and

31.2% were female. Mean age was 65.91±1.7% years. Major IABP complication (major limb ischemia) occurred in 2.6%. In hospital mortality was 21.1%. Female, advancing age and PVD (peripheral vascular disease) were independent predictors of a serious complication in their research. In our study 74.5% were male, 25.5% were female. Mean age was 58.08 years. Major limb ischemia occurred in 6.6%. No significant risk factor was identified because in PVD we used to put IABP with open technique under direct vision so there are remote chances of limb ischemia. In obese patients there is difficulty in insertion because of tortuous iliac artery so there are more chances of vessel perforation.[12] In one patient we had groin haematoma in an obese patient that need to be explored. Similar studies were conducted by Arceo[10], Mand AK[12], Meharwal[6], Christenson[4], and Cohen[16] (Table-7).

Table-7: Comparison of risk factors and complications with other studies

	Age (year)	Major Complications	Female Sex	PVD	Sheathed IABP	Small BSA
Cohen *et al*	65	11%	Yes	Yes	-	Yes
Arceo *et al*	60	4.7%	-	-	-	-
Mand`ak *et al*	-	5.7%	-	-	-	-
Christenson *et al*	-	2.1%	-	-	-	-
Meharawal *et al*	59.2	5.9%	-	Yes	Yes	-
Present study	58.08	6.6%	-	-	-	-

PVD=Peripheral vascular disease, BSA=Body surface area

Erdogan[11] analyzed 1211 cases. In his study he did comparison between sheath/sheath less technique for IABP insertion and observed vascular complications in 1211 patients. Limb ischemia was noted in 10.9% of patients. Peripheral vascular disease (PVD), diabetes and sheathed IABP were the major risk factors. In our study 12.3% patients got sheathed IABP and 87.7% sheath less. No significant association was observed because very less number of patients got sheathed balloon.

Oshima[9] discussed about the prolonged use for at least 10 days of IABP for heart failure. Mean duration of IABP support was 17±7 days. Femoral arteriovenous fistula was the only major IABP related complication in their study. In our study mean duration was 13.0±1.2 days. Again no significant association with duration was obtained mostly because the patients who are ventilated to such a long period of time are having acute peripheral shut down and to conclude a patient having limb ischemia is difficult.

Miessel[13] and colleagues described the importance of small sized catheter in their study .They inserted low profile IABP catheters by sheath less technique with a very low complication rate. They observed that large sized IABP resulted in high complication rate. The complications were mild limb ischemia (1.2%), minor bleeding episode (2.4%), 0.6% major puncture site bleeding, 1.2% patient with Pseudoaneurysm. These complications were less than using high profile >8 Fr catheter. In our study we put IABP according to body surface area of patient between 7–8 Fr, i.e., small BSA, small size of balloon and constant balloon volume of 40 cc so there are little chances of vessel trauma and limb ischemia.

Arafa[15] inserted transthoracic balloon pump in open-heart operation. Transthoracic technique is an alternative to routine transfemoral insertion in patients with severe PVD. There are very low complication rate but associated with high incidence of mediastnititis. In our study we used IABP in only one patient with transthoracic route in severely ill patient in ICU. Unfortunately she died on same day because of low cardiac output syndrome despite high inotropic support and IABP.

Cohen[16] described the sex and other predictors of IABP counterpulsation related complications in their prospective study of 1119 consecutive patients. Despite of advances of technique in IABP, its complication rate remain high. Mean age of patient in their study was 65 years. Major complication occurred in 11% of patients. They analyzed that PVD, female sex and small body surface area as independent predictors of major complication. In our study we used to put IABP in females of small size of 7 Fr according to body surface area so there were least chances of limb ischemia. Another fact was that, we used anticoagulation with heparin routinely in these patients to minimize thrombus formation.

Mortality due to vascular complications in 106 patients was 8.49% with $p<0.005$. In the study by Fergusson[3] mortality was 21.2%. The reason for low mortality rate in our study is probably the more number of patients receiving IABP peroperatvely very early before onset of any ischemia, i.e., 68.81% in our study compared to 16.1% in above mentioned study.

CONCLUSION

Use of IABP is very beneficial in cardiac surgery patients with low cardiac output and haemodynamic instability refractory to other treatment options. But it is significantly associated with vascular complications due to the use of IABP counterpulsation therapy.

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