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Complications Related to Intra-aortic Balloon Pump in Cardiac Surgery: A Decade Later

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Background. *Our centre in 1995 reported 26% of vascular complications in cardiac surgical patients treated with intra-aortic balloon pump (IABP). However, during the last decade there have been improvements in IABP technology and insertion techniques. We aimed to evaluate the impact of these changes on the incidence of IABP-related complications in cardiac surgery.*
Methods. *Demographics, indications, technique and complication rate in 186 consecutive patients treated with IABP from January 1994 to December 1998 (Group I) were compared with 323 consecutive patients treated with IABP from January 1999 to December 2003 (Group II) at our regional cardiothoracic centre. Data was variably expressed as mean with or without range and either standard deviation or range. Statistical significance was accepted at* $P<0.05$.
Results. *There were 121 (65%) and 194 (60%) males in Group I and II, respectively. The mean age was* 66 ± 12.1 *(17–88) years and the mean duration of IAPB use was 43.5 h (range 3–144 h). Overall complication rate was 10% in Group I and 2% in Group II whereas vascular complications accounted for 3% in Group-I and 1% in Group-II. Logistic regression analysis demonstrated cardiogenic shock being strongly correlated to in-hospital mortality (OR 4.68;* $P=0.004$*) followed by older age (OR 3.12;* $P=0.034$*) and ejection fraction* $<35\%$ *(OR 1.78;* $P=0.03$*).*
Conclusion. *The study demonstrated a significant decrease in the IABP-related complications even though complexity of cases referred for surgery has increased. Henceforth, the risk of 1% vascular complications should play little influence on decision-making regarding the use of IABP.*

Keywords: Intra-aortic balloon pump; Cardiac surgery; Trauma; Management.

Introduction

The indications for the use of intra-aortic balloon pump (IABP) in cardiac surgery include inability to wean the patient from cardiopulmonary bypass (CPB), post-operative low cardiac output syndrome, intractable ventricular arrhythmias and occasionally as a prophylactic use in patients with unstable symptoms or associated with poor ventricular function.[1] Previous studies have demonstrated that the augmented diastolic pressure results in a redistribution of coronary blood flow towards ischaemic areas of the myocardium, hence an improved myocardial supply/demand balance.[2,3] After load is reduced and diastolic pressure augmented, resulting in an increased stroke volume and cardiac output.[4]

Although technical advances such as percutaneous insertion;[5] smaller diameter catheters[6] and sheathless insertion[7] have simplified the use of IABP and made it more user friendly to cardiologists and cardiac surgeons, the published IABP-related complication rate (7.2–47%) still remains significantly high.[8–10] An earlier report from our centre identified peripheral vascular disease (PVD), female gender and diabetes as significant predictors and demonstrated high rate of vascular complications (26%) in post-surgical cardiac patients.[11] However, this study lacked in evaluating various other factors that might have led to complications associated with its use.[12]

Hence, the aim of this study was to evaluate the variations in the IABP insertion technique and its impact on the complication rate over a 10-year period in our centre.

Methods

Indications, technique and complication rate in 186 consecutive patients treated with IABP from January

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1994 to December 1998 (Group I) were compared with 323 consecutive patients treated with IABP from January 1999 to December 2003 (Group II) at the regional cardiothoracic centre. Their base-line demographics, clinical data, assessment of the lower limbs, haemodynamic status and pertinent medications were available from their respective case notes. The IABP (Datascope Corporation, Oakland, New Jersey, USA) was inserted via the femoral artery in the groin either pre, intra or post-operatively. The IABP inserted percutaneously (Seldinger technique) were removed without exposure of the femoral artery and bleeding controlled by direct pressure. Those, which had been inserted by open technique, were removed by re-exposure of the femoral artery and direct repair of the arteriotomy using 5.0 polypropylene (Ethicon Inc, USA) on the intensive care unit (ICU). There was no difference observed in evaluating complications associated with how the IABP was inserted though this to some degree reflected indications for use. We collected data based on the following endpoints:

- Limb ischaemia: decreased arterial flow as manifested by diminished pulse on flow Doppler that resolved following balloon removal, loss of sensation, abnormal limb temperature; or complication requiring surgical intervention.
- Bleeding: resulting in groin haematomas or continuous oozing from the puncture site.
- All-cause hospital mortality occurring from any cause during IABP or after IABP and the following variables were compared:

Demography and patient characteristics including age, sex, height, weight, diabetic status, PVD, previous myocardial infarction or CABG; indications for IABP insertion; catheter size and approach; concomitant use of anticoagulants and IABP related complications.

Statistics

Data was variably expressed as mean with or without range and either standard deviation or range. Where appropriate, statistical analysis was performed using logistic regression method, Chi-square test to compare categorical variables and Student's t test for continuous variables. Statistical significance was accepted at a level of $P<0.05$.

Results

The patients' demographics and indications for the use of IABP in Group-I and Group-II are summarized in Table 1. There were 121 (65%) and 194 (60%) males in Group I and II, respectively. The mean age was 66 ± 12.1 (17–88) years and the mean duration of IAPB use was 43.5 h (range 3–144 h). Overall complication rate was 10 vs 2% in Group I and Group II, respectively, and in-hospital mortality was 8%, however, the mortality rate was only 0.007% as a direct consequence of IABP. In our series, 96% of IABPs were inserted percutaneously. IABP related vascular complications accounted for 3% in Group-I and 1% in Group-II. There were, however, significant differences between the two groups in terms of peripheral vascular disease, use of anticoagulants, size and type of catheters (Table 1). The indications for use revealed interesting differences between the two groups with regards to its greater prophylactic use in cardiogenic shock in later years (1998–2003). Groin haematoma (3 vs 0.6%; $P<0.001$), limb ischaemia (2 vs 0%; $P<0.01$) and femoral artery trauma (4 vs 0.6%; $P<0.001$) were the attributable complications of IABP, significantly higher in Group-I as compared to Group-II (Table 2). Other complications included infection (0.2%), compartment syndrome (1%) and below knee amputation (0.1%). Multiple logistic regression analysis among patients supported by the IABP revealed risk factors for limb ischaemia, bleeding and in hospital mortality (Table 3). Female gender, associated PVD, and sheathed catheters with size >8.0 French were strongly associated with limb ischaemia. Access site bleeding occurred in 4% of case. The risk for bleeding included female gender, sheathed catheters, open femoral cut techniques and older age group (Table 3). Cardiogenic shock remained strongly correlated to in-hospital mortality (OR 4.68; $P=0.004$) followed by older age (OR 3.12; $P=0.034$) and ejection fraction $<35\%$ (OR 1.78; $P=0.03$). With regard to in-hospital mortality, no significant differences were detected between the two groups.

Discussion

IABP is an effective mean of supporting the failing circulation in patients at high risk of cardiovascular events post-operatively. However, the use of IABP is not without complications, rates as high as 47% have been reported.[8–10] This may relate to several considerable factors such as techniques used during insertion and indiscriminate use of anticoagulants in the absence of agreed protocol for anticoagulation for IABP. We have, therefore, examined various aspects of the procedure at our regional centre and compared

Table 1. Clinical and demographic characteristics

Variables	Group I ($N=186$)	Group II ($N=323$)	P-value
Age (years) mean	65.9±11.7 (20–88)	66.3±12.3 (17–75)	0.899
Sex (M/F)	121/65	194/129	0.234
Angina status (CCS)			
CCS 3	19 (10%)	45 (14.0%)	0.56
CCS 4	14 (7.5%)	20 (6.2%)	0.54
Dyspnoea status (NYHA)			
NYHA 3	56 (30.1%)	128 (39.6%)	0.23
NYHA 4	32 (17.2%)	39 (12.0%)	0.345
Ejection fraction <30–40%	18 (9.7%)	38 (11.7%)	0.78
Myocardial infarction	22 (11.8%)	43 (13.4%)	0.14
Diabetes mellitus (DM)	15 (8.1%)	33 (10.2%)	0.43
Hypercholesteremia	53 (28.5%)	99 (30.7%)	0.56
Creatinine (mmol/l) >200	5 (2.5%)	9 (2.8%)	0.76
Redo operation sequence	17 (9.1%)	51 (15.8%)	0.023
Operative priority (urgent)	27 (14.5%)	94 (29.1%)	0.01
Peripheral vascular disease	34 (18.2%)	120 (37.2%)	0.014
Preop use in high risk patients	8 (4.4%)	44 (13.6%)	0.021
Weaning from CPB	24 (12.9%)	43 (13.3%)	0.45
Cardiogenic shock	8 (4.30%)	46 (14.2%)	0.034
Anticoagulants	105 (56.5%)	284 (87.9%)	0.05
Size of catheter (<9.5 French)	57 (30.6%)	248 (76.8%)	0.009
Type of catheter (sheathless)	44 (23.6%)	305 (94.4%)	0.014
Approach (percutaneous)	176 (94.6%)	308 (95.4%)	0.78
Mean duration of IABP (hour)	43.0 (13–144)	42 (3–110)	0.82
Overall complications rate (%)	9.9	2.32	0.021
Vascular complications (%)	2.99	1.08	0.045

them between two 5-year cohorts of patients for whom data was available.

Until 1998, our centre was using 9.5 French IABP catheters with sheaths being used to secure access to the femoral artery. The use of IABP increased dramatically at an average of 15/year in 1994–1995 to 52/year in 2002–2003 by the surgeons at our regional centre in the background of its likelihood that pre-operative IABP insertion was associated with better survival. This is in agreement with the reported studies.[5–7] This may also be attributed to the nature of cardiac surgical patients being referred in the current era compared to previous years, perhaps because cardiological intervention has considerably increased which tends to cater one or two artery disease cases. Weaning of patients from cardiopulmonary bypass remains an important use of IABP, although expanding indications include its use to support high-risk patients with refractory ventricular failure, mechanical complications due to myocardial infarction, ischaemia related intractable ventricular arrhythmia, unstable refractory angina and cardiogenic shock.

The current study demonstrated a significantly lower rate of vascular complications associated with the use of IABP, in contrast to our earlier report.[11] This difference may merely reflect the increased use of smaller size balloon catheters, sheathless insertion techniques and percutaneous approach in the last 10 years at our centre. The importance of frequent use of IABP and, therefore, experience with their use should not be under-estimated. Evaluation of risks and benefits associated with prophylactic use of IABP, low molecular weight heparin and careful lower limb assessment before, during, and after counterpulsation using either with Doppler ultrasound; oxygen

Table 2. IABP attributable complications

Variables	Group I ($N=186$)	Group I ($N=323$)	P-value
Groin haematoma	6 (3.22%)	2 (0.62%)	0.03
Compartment syndrome	2 (1.07%)	0 (0.0%)	0.89
Limb ischaemia	4 (2.13%)	0 (0.0%)	0.023
Femoral artery trauma	7 (3.76%)	0 (0.0%)	0.01
Infection	1 (0.5%)	0 (0.0%)	0.78
Amputation	0 (0.00%)	0 (0.0%)	0.63

Table 3. Risk factors for cardiac surgery patients in which IABP used

Variables	Risk factors	OR	P-value
Groin haematoma	Female	1.26	0.034
	Sheathed	1.56	0.012
	Femoral cut-down	3.64	0.014
	Age	2.14	0.0134
Limb ischaemia	Female	2.79	0.021
	PVD	2.35	0.009
	Sheathed	1.97	0.043
	>8.0 French	3.79	0.0023
	Ejection fraction <35%	0.89	0.03
In hospital mortality	cardiogenic shock	4.68	0.004
	Age >65	3.12	0.034
	Ejection fraction <35%	1.78	0.03
	Urgent operation	1.34	0.023

saturation; ankle or brachial indices has helped reduce the complications associated with this device. Diagnosis of lower limb ischaemia in an unconscious, ventilated, cardiovascularly compromised patient can be difficult but diligent observation of the limb, serial use of Doppler together with prompt referral and close liaison with the vascular team has improved the outcome.

Cardiogenic shock remains the leading cause of death in our series. Even with successful coronary reperfusion, patient mortality has remained high. Few studies, however, have evaluated the relationship between cardiogenic shock and clinical outcome in patients with IABP support.[13] It is now clear that the cause of shock in patients with myocardial infarction is myocardial ischaemia and it has been suggested that the survival of patients with cardiogenic shock complicating myocardial infarction could be improved by coronary revascularisation following a period of IABP support. Recently, randomised studies have attempted to test whether emergency revascularisation does indeed improve survival in patients with cardiogenic shock complicating myocardial infarction but their data instead highlighted the limitations of coronary revascularisation.[14] Hence, cardiogenic shock must be treated more aggressively even if coronary revascularisation is successful, because without improvement in the shock state, the prognosis tends to be poor. Given that, the present study is a post-hoc analysis of prospectively gathered data and not a randomised one, the decision regarding deployment of IABP was left up to the cardiology/cardiac surgical team.

In conclusion we observed a significant decrease in vascular complications rate attributed to IABP between the two 5-year periods because of the significant increase in the number of IABP used. Evolving technology in balloon design, less invasive deployment techniques and appropriate anticoagulation therapy may have contributed to these encouraging results. We envisage an increase in the complexity of cardiac cases referred for surgery in the coming years and, therefore, expect even greater use of this cardiac support device. We believe that the decision to use IABP should not be influenced by a concern over the risk of vascular complications and will allow surgeons to safely extend its benefits to high risk patients to avoid haemodynamic instability that otherwise, often occurs.

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