Abstract

**Background and Objectives:** Intra-Aortic Balloon Pump (IABP) is device developed to augment coronary blood flow and improve systemic blood pressure in patients with circulatory failure. This study was undertaken to analyze morbidity and mortality benefit of IABP counterpulsation in patients with Acute Myocardial Infarction (AMI).

**Methodology:** This cross-sectional study done for three years in the Department of Cardiology of a tertiary care centre in North Karnataka from June 2009 to June 2012. Prior to the commencement of the study, ethical clearance was obtained from Human Ethics Committee. A total of 82 consecutive patients presenting with cardiogenic shock were included in the study. The patients satisfying selection criteria were informed in detail about the nature of the study and a written informed consent was obtained. The patients underwent electrocardiography and echocardiography. Based on the findings the indication for IABP was determined.

**Results:** Majority of the patients were males (85.4%) and the commonest age group was 51 to 60 years (40.2%) with the mean age of 57.73 ± 9.41 years. Most common Electrocardiogram (ECG) presentation was Anterior Wall Myocardial Infarction (AWMI) (40.2%). The commonest indication for placement of an IABP was Left Ventricular (LV) dysfunction (47.6%) and mean duration of IABP was 4 ± 1 days. Diagnostic catheterization was performed in 55 (67.1%) patients. Among them, 40 (72.7%) underwent Percutaneous Transluminal Coronary Angioplasty (PTCA) and 15 (27.3%) underwent surgery. Of the 82 patients, major IABP related complications occurred in six (7.3%) patients. The in-hospital mortality rate was 43.9% and 56.1% of the patients improved. Of the 46 patients who improved, majority (78.2%) had undergone revascularization while of the 27 patients who expired, 47.2% did not had revascularization (p=0.015). The outcome in patients who had undergone either PTCA or surgery was significantly favourable resulting in improvement (p<0.050).

**Conclusion and Interpretation:** IABP counterpulsation can be successfully employed for a wide variety of conditions in the AMI setting, providing significant haemodynamic support with rare major complications in a high-risk patient population.

**Keywords:** Acute Myocardial Infarction, Haemodynamic Support, Intra-aortic Balloon Pump, ST Elevation Myocardial Infarction
1. Introduction

Intra-Aortic Balloon Pump (IABP) is a device developed to augment coronary blood flow and improve systemic blood pressure in patients with circulatory failure. Development and advances in technology have increased the efficacy and safety of this device. With advancement like percutaneous insertion and sheath less device, risk of surgical cutdown and vascular complications has significantly reduced.

Intraaortic balloon pump counterpulsation was first developed in 1968. Intra-Aortic Balloon Pump works on the principle of counter-pulsation. Balloon of the device inflates during diastole and deflates during systole. Overall effect of which causes reduced afterload, increased left ventricular forward flow and increased coronary perfusion.

Haemodynamic effects of IABP therapy include aorta (systolic and diastolic pressure), left ventricle (systolic and end-diastolic pressure, volume, wall, tension) and heart (afterload, preload, cardiac output, blood or coronary blood flow). Intraaortic balloon pump therapy is indicated for acute myocardial infarction, refractory Left Ventricular (LV) failure, cardiogenic shock, refractory ventricular arrhythmias, acute Mitral Regurgitation (MR) and Ventricular Septal Rupture (VSR), cardiomyopathies, catheterization and angioplasty, sepsis, refractory unstable angina. IABP is associated with vascular complications like aneurysm, bleeding and haematoma. It is associated with many major and minor complications. It is contraindicated in patients with severe aortic regurgitation, aortic dissection, abdominal aortic aneurism, end stage of heart disease, aortic stents and peripheral vascular disease. It is associated with vascular complications like aneurysm, bleeding and haematoma. It is associated with major complications like aortic dissection, compartment syndrome, sepsis, acute renal failure and cardiac tamponade.

According to the recent Task Force on Practice Guidelines of the American Heart Association (AHA) and American College of Cardiology (ACC), class I indications for IABP use in Acute Myocardial Infarction (AMI) include: acute mitral regurgitation or VSR complicating AMI. Post-myocardial infarction it acts as a bridge to angiography and revascularization in patients with cardiogenic shock, recurrent intractable ventricular arrhythmias causing hemodynamic instability and; refractory post myocardial infarction angina.

Recent publications have focused on improving preventive measures but, less attention has been placed on the acute management of ST Elevation Myocardial Infarction (STEMI). Despite considerable improvement in the process of care for patients with STEMI, room for improvement exists. With improved equipment and ever expanding indications for the use of IABP still data regarding clinical outcome of IABP in India is scarce. Hence, this study was undertaken to analyze morbidity and mortality benefit of IABP counterpulsation in patients with Acute Myocardial Infarction (AMI).

2. Methodology

This cross-sectional study was conducted over a period of three years in the Department of Cardiology of a tertiary care centre in North Karnataka from June 2009 to June 2012. Prior to the commencement of the study, ethical clearance was obtained from Human Ethics Committee.

A total of 82 consecutive patients presenting with cardiogenic shock that is, low blood pressure (<90 mm Hg) and signs of hypoperfusion (cool, clammy skin, oliguria, or altered sensorium), nonresponsive to fluid resuscitation or pressors with Cardiac index of ≤2.2 lit/min/ m² and PCWP ≥ 18 mm of Hg were included in the study. Patients presenting with cardiogenic shock having high risk unstable angina and non STEMI were excluded from the study. Minor ischemia involved decreased arterial flow, as manifested by a diminished pulse that resolved with balloon removal, not otherwise resulting in impairment of organ function. Major limb ischemia was considered as a loss of pulse or sensation, or abnormal limb temperature or pallor requiring surgical intervention. Minor hematoma and oozing from a puncture site not requiring blood transfusion or surgical intervention was defined as non severe bleeding and severe bleeding was as requirement of blood transfusion or surgical intervention, or association with haemodynamic compromise.

The patients satisfying selection criteria were informed in detail about the nature of the study and a written informed consent was obtained. Patients were interviewed and demographic data such as age, sex and the chief presenting complaints were noted. The patients underwent ECG and echocardiography. Based on the findings the indication for IABP was determined.

Appropriate balloon size and catheter is chosen as per the patients height. Even though balloon insertion is done under fluoroscopic guidance, balloon site is regularly checked by chest x ray. All peripheral pulsations checked regularly. All patients were on heparin with regular activated Partial Thromboplastin Time (aPTT) check up. The balloon was weaned off gradually in terms of volume and
ratio. The patients were evaluated for complications and outcome.

3. Statistical Analysis

The categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test. Continuous data was expressed as mean ± standard deviation. Categorical data was analysed with chi-square test and a probability (‘p’) value of less than or equal to 0.05 was considered as statistically significant.

4. Results

Majority of the patients were males (85.4%) with male female ratio of 5.83:1 and the commonest age group was 51 to 60 years (40.2%). The ranged between 34 being minimum to 75 being maximum and the mean age was 57.73 ± 9.41 years (Table 1).

Most common ECG presentation was AWMI (40.2%) followed by inferior wall myocardial infarction (29.3%). Cardiogenic shock was noted in 61% of the patients. Placement of an IABP in AMI patients was most frequently indicated for LV dysfunction (47.6%) and the mean duration of IABP use was 4 ± 1 days. Diagnostic catheterization was performed in 55 (67.1%) patients. Among them, 40 (72.7%) underwent percutaneous transluminal coronary angioplasty (PTCA) and 15 (27.3%) underwent surgery. Among these, PTCA to single vessel disease was done in 23 (57.5%) patients. Operative procedure was performed in 15 (27.3%) patients. Out of these VSR Closure with coronary Artery Bypass Grafting (CABG) was done in 8 (53.3%) patients (Table 2).

| Characteristics | Sub groups | Distribution (n=82) |
|-----------------|------------|--------------------|
|                 | Number     | Percentage         |
| Sex             | Male       | 70                 | 85.4 |
|                 | Female     | 12                 | 14.6 |
|                 | Total      | 82                 | 100.00 |
| Age (Years)     | 31 to 40   | 8                  | 9.8  |
|                 | 41 to 50   | 10                 | 12.2 |
|                 | 51 to 60   | 33                 | 40.2 |
|                 | 61 to 70   | 27                 | 32.9 |
|                 | > 70       | 4                  | 4.9  |
|                 | Total      | 82                 | 100.00 |

Table 2. ECG findings, Indication for IABP, location of VSR and procedure

| Variables                              | Findings                        | Distribution |
|----------------------------------------|---------------------------------|--------------|
| ECG findings (n=82)                    | AMWI                            | 33           | 40.2 |
|                                       | AWMI with RBBB                  | 16           | 19.5 |
|                                       | AWMI with LBBB                  | 5            | 6.1  |
|                                       | AWMI with complete heart block  | 4            | 4.9  |
|                                       | Inferior wall myocardial infarction | 24          | 29.3 |
| Indication for IABP (n=82)             | Left ventricular dysfunction    | 39           | 47.6 |
|                                       | Bridge to revascularization     | 18           | 22.0 |
|                                       | Mechanical complications        | 25           | 30.5 |
| Mechanical Complications (n=25)        | VSR                             | 8            | 32.0 |
|                                       | MR                              | 17           | 68.0 |
|                                       | Total                           | 25           | 100.00 |
| Location of VSR (n=8)                  | Apical                          | 5            | 62.5 |
|                                       | Mid muscular                    | 3            | 37.5 |
|                                       | Total                           | 8            | 100.00 |
| Investigations (n=82)                  | Coronary angiography            | 55           | 67.1 |
|                                       | Could not be performed / refused| 27           | 32.9 |
| Procedures (n=55)                      | Total                           | 82           | 100.00 |
|                                        | PTCA                            | 40           | 72.7 |
|                                        | Surgery                         | 15           | 27.3 |
|                                        | Total                           | 55           | 100.00 |
| PTCA (n=40)                            | LAD                             | 24           | 60.0 |
|                                        | RCA                             | 4            | 10.0 |
|                                        | LAD + LCX                       | 5            | 12.5 |
|                                        | LAD + RCA                       | 4            | 10.0 |
|                                        | LCX + RCA                       | 3            | 7.5  |
|                                        | Total                           | 40           | 100.00 |
| Surgery (n=15)                         | CABG with VSR closure           | 8            | 53.3 |
|                                        | CABG                            | 7            | 46.7 |
|                                        | Total                           | 15           | 100.00 |
Of the 82 patients, major IABP related complications occurred in six (7.3%) patients of which, five patients had major bleeding who required blood transfusion and one patient had external iliac artery occlusion who underwent embolectomy (Table 3).

The in-hospital mortality rate was 43.9% and 56.1% of the patients improved. Of the 46 patients who improved, majority (78.2%) had undergone revascularization while of the 27 patients who expired, 47.2% did not have revascularization and this difference was statistically significant (p=0.015). The outcome in patients who had undergone either PTCA or surgery was significantly favorable resulting in improvement (p<0.050) (Table 4). The major causes of mortality were arrhythmias (45.7%), acute renal failure (34.2%), infection and multiorgan dysfunction in (22.8%).

5. Discussion

There is conflicting and insufficient evidence regarding the use of IABP therapy. The meta-analysis of various cohort studies in STEMI complicated by cardiogenic shock has supported IABP therapy adjunctive to thrombolysis. Observational data have not supported IABP therapy adjunctive to primary percutaneous coronary intervention in previous studies. The pooled randomized data currently available is not in support of IABP insertion in high-risk STEMI.

In our study the major indication for IABP insertion was observed to be LV Dysfunction (47.6%). The in hospital mortality observed in the study that is 43.9% was comparable with another study by Kapadia et al. in 2004 where in hospital rate was 40% even though the overall duration of IABP in our study was longer than study done previously. In-hospital mortality was 20% (1098/5495) as reported by the Benchmark Counterpulsation Registry and 45% (90/201) from the Cardiology Center, Geneva.

Eventhough there was survival benefit with IABP use in SHOCK trial, there was no mortality benefit shown in revascularised arm. (Mortality of 62% with IABP and 54% without IABP use. P= 0.743) In comparison, Diagnostic catheterization was performed in 55 (67.1%) of patients and all these patients underwent coronary revascularization before hospital discharge in our study. The mortality of patients with AMI requiring IABP support was significantly high in those in whom angiography and revascularization were not performed.

Earlier studies have shown the incidence of major balloon-related complications to be low (2.8%) but in our study it has been observed in 7.3% of the patients. IABP insertion was found to improve the mortality benefit ratio significantly in patients especially as bridge to revascularization.

| Procedure | Outcome | Revascularization | Total | p value |
|-----------|---------|------------------|-------|---------|
|           |         | Done | Non done |       |         |
| Overall   | Improved| 36   | 10 | 21.74  | 46 | 92.00  | 0.015|
|           | Expired | 19   | 17 | 47.22  | 36 | 72.00  |       |
|           | Total   | 55   | 27 | 32.93  | 82 | 100.00 |       |
| PTCA      | Present | 25   | 10 | 28.57  | 35 | 70.00  |       |
|           | Absent  | 15   | 17 | 53.13  | 32 | 64.00  | 0.041|
|           | Total   | 40   | 27 | 40.30  | 67 | 100.00 |       |
| Surgery   | Present | 11   | 10 | 47.62  | 21 | 42.00  | 0.024|
|           | Absent  | 4    | 17 | 80.95  | 21 | 42.00  |       |
|           | Total   | 15   | 27 | 64.29  | 42 | 100.00 |       |
larization as out of 55 revascularized patients 36 survived (78.2%; p=0.015).

The cause benefit of survival being IABP insertion or revascularization is still unclear. It may be possible that revascularization alone may have benefitted these patients with increased survival rate however the advantage of IABP insertion cannot be ruled out. Further study regarding this is required.

6. Conclusion

IABP insertion benefit was observed in patients with a bridge to revascularization procedure in pre-cardiac surgery/pre-angioplasty, thus affording a better haemodynamic support in high-risk group. Overall in-hospital mortality was high but those who underwent successful revascularisation it was observed to be significantly low. IABP counterpulsation can be successfully employed for a wide variety of conditions in the AMI setting, providing significant haemodynamic support with rare major complications in a high-risk patient population. In other studies use of IABP was not associated with mortality or morbidity benefit however our study has showed definite mortality benefit when associated with revascularization. In our study we conclude that even though mortality is high in those patients requiring IABP it is still useful if revascularisation is taken place .It is cost effective when compared to LV assist devices especially in developing countries like India.

7. References

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