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AN ANALYSIS OF INDICATIONS, TIME OF INITIATION AND MORTALITY IN ADULT CARDIAC SURGICAL PATIENTS WITH INTRA-AORTIC BALLOON PUMP SUPPORT.

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ABSTRACT

Objective: To determine the frequency, indications, time of initiation and outcome of intra-aortic balloon pump (IABP) therapy in adult cardiac surgical patients over the period of one year in Queen Alia Heart Institute (QAHI). Methods: From January 2009 to January 2010, 1872 consecutive adult open heart surgical procedures were performed. This included 1361 isolated coronary artery bypass grafting (CABG) procedures, 359 isolated valve procedures (one or more valves), 112 combined CABG & valve procedures and 40 other procedures (ASD, VSD, cardiac tumors). Patients were divided into three groups in relation to the time of insertion of intra-aortic balloon pump and initiation of counter-pulsation: Pre-operative, intra-operative and postoperative groups. Mean age of patients was 59 years (range, 41 to 78 years) and 68 % of patients were males. In hospital mortality for each group was compared at 7 days and 30 days. Chi-square test was used to investigate the relationship between the mortality rate at 7 days and 30 days with other factors. The result was considered significant if the p-value was less than 0.05. Results: Intra-aortic balloon pump support was used in 121 patients (out of 1872 patients), which constituted 6.46 % of all adult cardiac surgical patients. Weaning from cardiopulmonary bypass (CPB) was the most common indication of IABP use (66.9%). Preoperative insertion and initiation of intra-aortic balloon pump counterpulsation had significant lower 7 day mortality than the intra-operative and post-operative uses (p-value =0.022). At 30 days the mortality was least in the intra-operative group and most in the post-operative group, the p-value was not significant (p-value=0.087). The use of intra-aortic balloon was associated with less mortality for isolated coronary artery bypass grafting (CABG) than the combined (CABG + valve) surgeries or isolated valvular surgeries at 7 and 30 days. The p-value was significant at 7 days (p-value=0.014), and was also significant at 30 days (p-value=0.029). Female patients who had IABP support had higher mortality rates than male patients at 7 days and 30 days. Results were statistically not significant when relationship between gender and mortality at 7 days was investigated (p-value=0.114) and between gender and 30 days mortality (p-value=0.081). Conclusions: Weaning from cardiopulmonary bypass (CPB) is the most common indication for counter-pulsation. Pre-operative prophylactic uses were found to be less common and were associated with lower mortality rates. Therefore, earlier IABP therapy as part of surgical strategy in high risk patients may help improve the outcome. Higher mortality rates were observed in patients who had IABP support initiated post-operatively, in female patients or in isolated valve(s) procedures. Our results are compared favourably with others reported in the literature.

Key words: Intra-aortic balloon pump (IABP), cardiac surgery, cardiopulmonary bypass (CPB), mortality, coronary artery bypass grafting (CABG).

INTRODUCTION

Intra-aortic balloon pump (IABP) is the most commonly used mechanical circulatory assist device. The first clinical experience with the IABP was in patients with cardiogenic shock after myocardial infarction. In 1958 Harken et al first described a method of removing blood volume during systole and replacing the blood volume during diastole, but due to difficult synchronization with cardiac cycle, it had limited success. In 1962 Moulopoulus et al at the Cleveland clinic invented the first prototype of the IABP whose inflation and deflation were timed to cardiac cycle. In 1968 further development of the IABP by Kantrowiz et al occurred. During the first years of use, the balloon needed surgical intervention for insertion and removal, but since 1979 percutaneous insertion by the

Seldinger's technique of smaller sizes of balloon catheters became available. The IABP was used since 1970s to facilitate weaning of cardiac surgical patients from cardiopulmonary bypass, when weaning is difficult or impossible by conventional means (1). The balloon inflates during diastole, results in augmentation of aortic diastolic pressure, and deflates just prior to the onset of systole, reducing impedance of left ventricular ejection. It reduces myocardial work and myocardial oxygen consumption by decreasing afterload; it increases coronary blood flow, cardiac output and perfusion of vital organs (2). The IABP device consists of a double lumen catheter with a polyethylene balloon attached at its distal end, where the outer lumen is used for the delivery of gas (helium), while the inner lumen can be used to monitor intra-aortic blood pressure. It also consists of a console with a pump to drive the balloon. The appropriate balloon size is selected on the basis of the patient's height. The diameter of the balloon, when fully expanded, should not exceed 80-90% of the diameter of the patient's descending thoracic aorta. The most common route of insertion is the femoral artery. Other routes are the axillary, subclavian or iliac arteries; also transthoracic insertion into the ascending aorta intraoperatively is described by Burack et al. (3). The balloon should be positioned so the tip is 1cm distal to the origin of the left subclavian artery. Contraindications of IABP use are severe aortic valvular insufficiency, aortic dissection and severe peripheral vascular disease. Complications of IABP are either; balloon related with perforation or rupture of the balloon causing gas embolization, or vascular complications with arterial injury, aortic perforation or dissection, femoral artery thrombosis, peripheral embolization or limb ischemia. Other possible complications are infection, malpositioning and entrapment of the balloon.

In the last few years there was growing evidence that prophylactic use of IABP in high risk patients undergoing cardiac surgery is associated with less mortality than intraoperative or postoperative use (4).

METHODS

Data were collected retrospectively from cardiac surgery registers; and a register for intra-aortic balloon pump (IABP) patients.

PATIENT POPULATION AND DATA

From January 2009 to January 2010, 1872 consecutive adult open heart surgical procedures were performed. This included 1361 isolated coronary artery bypass grafting (CABG) procedures, 359 isolated valve procedures (one or more valves), 112 combined CABG & valve procedures and 40 other procedures (ASD, VSD, cardiac tumors). Patients were divided into three groups in relation to the time of insertion of intra-aortic balloon pump and initiation of counter-pulsation: Pre-operative, intra-operative and postoperative groups. Non-surgical patients supported with IABP were excluded from the study. Mean age of patients was 59 years (range, 41 to 78 years) and 68 % of patients were males. In hospital mortality (defined as death within the same hospital admission regardless of cause) for each group was compared at 7 days and 30 days. Chi-square test was used to investigate the relationship between the mortality rate at 7 days and 30 days with other factors. The result was considered significant if the p-value was less than 0.05.

RESULTS

Frequency of use of IABP support:

Intra-aortic balloon pump support was used in 121 patients (out of 1872 patients), which constituted 6.46 % of all adult cardiac surgical patients, 12.5 % of patients undergoing combined CABG & valve procedures (14 patients out of 112), 7.64 % of patients undergoing isolated coronary

artery bypass grafting (104 patients out of 1361) procedures and 0.083 % of patients undergoing isolated valve surgery (2 patients out of 359).

Indications and time of insertion:

10 patients (8.26% of indications) received pre-operative intra-aortic balloon pump (IABP) support either; as a prophylactic measure prior to elective open heart surgery in high risk patients (8 patients or 6.6 % of indications) or for pre-operative cardiogenic shock prior to emergency open heart surgery (2 patients or 1.65 % of indications). 81 patients (66.9 % of indications) required intra-operative IABP support to help weaning from cardio-pulmonary bypass (CPB) machine. 30 patients (24.8 %) required post-operative IABP support in post-surgical intensive care unit due to cardiogenic shock, increasing requirements and poor response of inotropic support, it was also used for post surgical septic shock in two patients (1.65 % of indications).

Mortality:

Overall early mortality rate of CABG surgery at the year of 2009 was 5% and for valve surgery 2%. Patients who required IABP support were found to have a 7 day mortality rate of 28.01 %, 30 day mortality rate of 34.7 %.

Mortality and time of initiation of IABP support:

The preoperative group had a 10 % mortality rate at 7 days (one patient died and 9 survived), 30 % at 30 days (three patients died and seven survived). The Intra-operative group had 23.4 % mortality rate at 7 days (19 patients died and 62 survived), 27.1 % at 30 days (28 patients died and 53 survived). The post-operative group had 46.7 % mortality rate at 7 days (14 patients died and 16 survived), 56.7 % at 30 days (17 patients died and 13 survived). The results show that preoperative insertion and initiation of intra-aortic balloon pump counterpulsation had significant lower 7 day mortality than the intra-operative and post-operative uses (p-value =0.022). At 30 days the mortality was least in the intra-operative group and most in the post-operative group, the p-value was not significant (p-value=0.087). Table (1)

Mortality and type of surgery:

Over the one year period only 2 patients who underwent isolated valve surgery (out of 359 patients) had IABP support and both died within 48 hours. 14 patients who underwent combined CABG & valve surgery (out of 112) needed IABP and the mortality rates were 35.7 % (5 patients died and 9 survived) at 7 days and 57.1 % (8 patients died and 6 survived) at 30 days. Intra-aortic balloon pump counter-pulsation (IABP) was used in 104 patients who underwent isolated coronary artery bypass grafting (CABG) procedures (out of 1361), the 7 days mortality rate was 25% (26 patients died and 78 survived), and the 30 days was 35.5% (37 patients died and 67 survived). The use of intra-aortic balloon was associated with less mortality for isolated coronary artery bypass grafting (CABG) than the combined (CABG + valve) surgeries or isolated valvular surgeries at 7 and 30 days. The p-value was significant at 7 days (p-value=0.014), and was also significant at 30 days (p-value=0.029). Table (2)

Mortality and gender:

When patients were divided by gender, mortality rate in females was 37.8% at 7 days (14 female patients died and 23 survived) and 51.3% at 30 days (19 female patients died and 18 survived). Mortality at 7 days in males was 23.8% (20 male patients died and 64 survived), while the 30 days mortality in males was 34.5% (29 patients died and 55 survived). Results were statistically not significant when relationship between gender and mortality at 7 days was investigated (p-value=0.114) and between gender and 30 days mortality (p-value=0.081).

Table (1): Mortality and time of initiation of IABP support:

Mortality Rate	Pre-op. IABP (n=10)	Intra-op. IABP (n=81)	Post-op. IABP (n=30)	p-value
7 days	1 (10 %)	19 (23.4 %)	14 (46.7%)	0.022
30 days	3 (30 %)	28 (34.6 %)	17 (56.7%)	0.087

Table (2): Mortality and type of surgery:

	Adult cardiac surgical patients	CABG	Valve	Combined	Other
Total No. of cases	1872	1361	359	112	40
Patients required IABP	121	104	3	14	0
% of patients who required IABP	6.46%	86%	2.5%	11.6%	0%

DISCUSSION

IABP is a well established mechanical support device for temporary assistance in the treatment of the failing heart. IABP could be used preoperatively, intraoperatively or postoperatively. However, despite the wide use of the device, the optimal timing and use of IABP remains controversial (5). Time of insertion has been showed to affect hospital mortality, which in our study was ranging from 10% to 30% for preoperative insertion, from 23.4% to 27.1% for intraoperative insertion and from 46.7% to 56.7% for postoperative insertion.

Pre-operative treatment with IABP in high risk CABG is an effective modality to prepare these patients to have their myocardial revascularization in an as nonischemic situation as possible, which resulted in significantly lower hospital mortality, as we found in our investigation. Reduction in hospital mortality in pre-operative IABP support before high risk open heart surgery was demonstrated by several studies (6,7), also a reduction in hospital stay and cost-effectiveness of preoperative IABP in patients with ejection fraction of 0.25 or less was reported by Dietl et al. (8)

Incremental risk factors for perioperative death have been reported by several investigators (9). In a large retrospective study by Trochiana et al (10) independent predictors of death with balloon pump support were insertion in the operating room or intensive care unit, transthoracic insertion age, mitral valve replacement, prolonged cardiopulmonary bypass (CPB), urgent or emergency operation, preoperative renal dysfunction, complex ventricular ectopy, right ventricular failure, and emergency reinstitution of CPB.

The need of IABP support perioperatively in cardiac surgical patients is often predictable in patients with severe left ventricular impairment, low ejection fraction, left main disease, old age, previous cardiac surgery, emergency operation and recent myocardial infarction. A risk model based on preoperative clinical data to identify high-risk patients and predict the need for IABP insertion during CABG was suggested in a recent study by Miceli et al. (11). In our study, the most common use of IABP was to help weaning from cardiopulmonary bypass. The initiation of IABP postoperatively due to low cardiac output syndromes was usually associated with the use of high inotropic support, and high mortality.

The higher mortality rates among female patients treated with IABP perioperatively is related to the higher mortality in females after CABG operations. The most common explanations for this observation have centered on the fact that women have smaller, more technically challenging coronary vessels, less frequent use of internal mammary artery (IMA) grafting, women's advanced disease and increased age of presentation for surgery. (12, 13, 14)

Even though we have demonstrated the lower mortality rates of preoperative insertion and treatment with IABP in high risk-patients undergoing CABG, it must be emphasized that IABP therapy is associated with nonnegligible morbidity. The most common morbidities are early vascular complications, caused by either flow impairment as a result of partial or complete obstruction by the IAB catheter itself or distal embolization, resulting in leg ischemia. We observed overall vascular complications in 10 patients (8.2%), reversible limb ischemia occurred in 7 patients (5.7%), that resolved after removal or replacement of the balloon. Femoral embolectomy was needed in 3 patients (2.4%). However, no patient in our series required amputation, and no deaths attributable to IABP use were noted. The use of smaller IABP catheters, have contributed to the lower incidence of major IABP complications. (15, 16)

We compared results from our study with others reported in the literature. The in-hospital mortality for patients who needed IABP support of our study was 28.09% (34/121), 20% (1098/5495) as reported from the Benchmark Counterpulsation Registry(17), 45% (90/201) in-hospital mortality from Cardiology Center, Geneva(18) and 32.85% (23/70) in-hospital mortality from Hinduja National Hospital and medical research center, Mumbai, India.(19)

LIMITATIONS

Limitations of the study were the observational retrospective nature of the study. Also, the study population comes from a single institution study.

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