The Professional Medical Journal
www.theprofesional.com

DOI: 10.29309/TPMJ/18.4605

ORIGINAL PROF-4605

ASSIST DEVICES IN CARDIAC SURGERY;
RE-STERILIZED INTRA-AORTIC BALLOON PUMP CATHETERS

1. FCPS
Assistant Professor
Department of Cardiac Surgery
National Institute of Cardiovascular Diseases (NICVD),Karachi, Pakistan.
2. FCPS
Assistant Professor
Department of Cardiac Surgery
National Institute of Cardiovascular Diseases (NICVD),Karachi, Pakistan.
3. FCPS
Associate Professor
Department of Cardiac Surgery
National Institute of Cardiovascular Diseases (NICVD),Karachi, Pakistan.
4. FRCS
Associate Professor
Department of Cardiac Surgery
National Institute of Cardiovascular Diseases (NICVD),Karachi, Pakistan.
5. FRCS
Professor
Department of Cardiac Surgery
National Institute of Cardiovascular Diseases (NICVD),Karachi, Pakistan.

Correspondence Address:
Dr. Saad Bader Zakai
National Institute of Cardiovascular Diseases (NICVD)
Rafiqui (H.J) Shaheed Road,
Karachi, 75510, Pakistan.
defencedoc@gmail.com

Article received on:
27/12/2017
Accepted for publication:
15/08/2018
Received after proof reading:
03/12/2018

Saad B. Zakai[1], Iqbal Hussain Pathan[2], Sohail K Bangash[3], Tariq A. Siddiqi[4], Fazle Rabbi[5]

ABSTRACT… Objectives: IABP is the most frequently used assist device in cardiac surgery. However, due to the poor socioeconomic status in our country, it is not always possible to use a brand new IABP when required. In these circumstances we use re-sterilized IABP catheters. Our aim was to compare the outcome of re-sterilized versus new IABP catheters in the set of patients who were provided surgery for IHD free of cost in a tertiary care hospital. **Study Design:** Retrospective study. **Period:** January 2007 to December 2013. **Setting:** National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan. **Methods:** 3560 CABG procedures were performed. Those patients who could not afford a new IABP catheter were provided with the re-sterilized balloon catheters, free of cost. Total IABP usage was 286(8%) patients, of which the new balloon catheter was used in 214patients [74.8% (groupI)]. Re-sterilized catheters were used in 72patients [25.2% (groupII)]. All patients were screened for HIV, Hepatitis- B and Hepatitis-C. 12(16.6%) of the balloon catheters were resterilized more than once and 3(4.1%) of these on three occasions. **Results:** The mean age of the patients was 52.59±13.32 years. 69 (24.1%) of the patients were female. The mode of insertion (sheath less versus with sheath) was found to be an independent risk factor for the development of complications. The overall incidence of complications (p=0.29) was 6.9%. The incidence of balloon catheter related complications was 1.75%. When the two groups were compared with regard to morbidity and mortality, the results were found to be statistically insignificant. **Conclusion:** Use of re-sterilized IABP catheters is safe. However, strict guidelines should be instituted and followed for this purpose.

Key words: Artery/arteries; Ischemia; Wound Infection; Coronary Artery Bypass Grafting (CABG); Circulatory Assistance, Temporary.

Article Citation: Zakai SB, Pathan IH, Bangash SK, Siddiqi TA, Rabbi F. Assist devices in cardiac surgery; re-sterilized intra-aortic balloon pump catheters. Professional Med J 2018; 25(12):1796-1804. **DOI:** 10.29309/TPMJ/18.4605

INTRODUCTION

Harken[1] in 1958, came up with the idea of Intra-Aortic Balloon Pump counterpulsation (IABP), by highlighting that a balloon placed over a catheter located in thoracic aorta will cause diastolic augmentation. It was launched experimentally by Moulopoulos and associates in1962[2] and brought into clinical practice by Kantrowitz and associates in 1968.[3]

Being amongst the commonly used ventricular assist devices, especially in high risk patients undergoing cardiac surgery both in the preoperative and perioperative setting[4], it has also been shown to be effective in reducing mortality and morbidity after acute myocardial infarction[5], in cardiogenic shock[3] and in severe left ventricular dysfunction.[6] It also plays a pivotal role in stabilizing patients who are undergoing angioplasty[7] Its functions include[1] fall inventricular afterload,[2] increase in diastolic coronary perfusion and[3] subendocardial perfusion improvement.[8]

Over the last decade, there has been a rapid development in the techniques and approaches of interventional cardiology, thus the characteristics of patients undergoing CABG has diversified extensively.[9] A significant proportion of patients coming for surgical intervention have one or more of the factors: redo cases, poor left ventricular function (ejection fraction <0.30%), severe left main coronary artery stenosis, or diffuse coronary artery disease.[10,11,12] Thus, these patients have very high chances of developing haemodynamic instability perioperatively and require IABP support.

Pakistan[13] has a very high incidence of coronary artery disease (CAD). About 100.000 individuals suffered from acute myocardial infarction (AMI) in calendar year 2002.[14] Patients from the lower socio-economic group who make up the majority of the population are generally unable to afford the cost of coronary bypass surgery. The cost of CABG surgery is approximately US$2000.00, which has been subsidized to US$500.00 at our institute. For those who cannot afford to pay even this amount, surgery is provided free of cost. The cost of a new IABP catheter is approximately US$ 700.00, which has been subsidized to US$ 250.00 at our institute. We use re-sterilized IABP catheters only in emergency situations, in those patients who cannot afford to pay for a new one.

The study was undertaken on patients who had coronary revascularization over the last seven years at our institute. We evaluated the effect of using resterilized versus new IABP catheters and balloon related morbidity and mortality.

MATERIAL AND METHODS

This is a retrospective study of 3560 patients who underwent coronary artery bypass grafting (CABG), with or without associated procedures between January 2007 to December 2013. A total of 286 patients (8.03%) received IABP support. A new IABP catheter was used in 214 patients (74.8%) (group I) and a resterilized catheter in 72 patients (25.2%) (group II).

Demographic and clinical variables studied included age, sex, body surface area, hypertension, diabetes mellitus, peripheral vascular disease (PVD), smoking, hypercholesterolemia, obesity and family history. The IABP related variables which were studied included technique of insertion (per-cutaneous vs open, femoral vs transaortic), mode of balloon insertion (with sheath vs sheathless), diameter of balloon catheter, volume of balloon, duration of IABP therapy and catheter related complications.

Technique of IABP Insertion

Datascope (DatascopeInc. Fairfield NJ, USA) and Arrow (Arrow International Inc, Reading, PA, USA) catheters and their corresponding console units were used. Techniques used for insertion were percutaneous (94.8%), open (4.5%) and trans-thoracic (0.7%). The sizes of the balloons were7 and 8 French, calculated according to body surface area. The volumes of the balloon were either 34cc or 40cc. Insertion techniques involved either sheathless (63.3%) or with sheath (36.7%) methods. All resterilized catheters were checked for possible leakage with an air filled 50cc syringe, before insertion. Informed consent was obtained. The position of the balloon catheter was confirmed by chest X-ray.

Post IABP Protocol

All patients were started on subcutaneous Enoxaparin (dosed by weight at 1mg/kg/per dose), twice daily, 24 hours postoperatively. Peripheral pulses of both lower limbs were monitored by Doppler and peripheral pulses chart was maintained on 2 hourly basis in the intensive care unit (ICU).

The definitions of IABP-related complications from the Benchmark registry (15) were used. Major limb ischemia was defined as" a loss of pulse or sensation, or abnormal limb temperature or pallor, requiring surgical intervention". Minor ischemia was defined as" decreased arterial flow as manifested by diminished pulse that resolved with balloon or sheath removal, and not resulting in any impairment of body function". An "association with hemodynamic compromise, requiring blood transfusion or surgical intervention" defined severe bleeding. Non-severe bleeding involved" minor hematomas and oozing from puncture site that did not require blood transfusion or surgical intervention". The IABP failure was defined as "poor augmentation, inability to deploy or any catheter leak suggested by blood inside the catheter tubing or gas loss".

Method of Sterilization

The IABP catheters were sterilized with ethylene oxide in the Bio-Gas BM-4 Programatic-158L sterilizator (Argentina). The times and temperatures of sterilization are 2, 4, 6hrs and 60˚C, 45˚C, 30˚C respectively. The ventilation time ranges from 1-10hours, depending on the material. At our institute, the IABP catheters are

first thoroughly washed with tap water, arterial line flushed with normal saline, covered and then allowed to dry. The introducer wire is then re-inserted and the catheter sent to Central Sterile Supply Department (CSSD) for resterilization. The complete set of introducer elements are sent to the CSSD separately after insertion of every new catheter.

Data Analysis Procedure

Statistical Packages for Social Science (SPSS-16) were used to analyze data. Mean and standard deviation were estimated for quantitative measurements and proportion and percentage were computed for qualitative observations. Chi-square and Fisher exact test were applied to compare proportion difference between groups for qualitative observations especially complications while independent sample t test was used to compare mean difference. $P \leq 0.05$ was considered significant.

RESULTS

A total of 3560 patients underwent CABG with or without associated procedures between January 2007 and December 2013. Out of these, 286 (8 %) patients required IABP therapy. The new balloon catheter was inserted in 214 (74.8%) patients and the resterilized balloon in 72 (25.2%). Patients. There was an increase in the frequency of IABP use over the study period (Table-I). In the year 2007, 23 balloon catheters were inserted which increased to 42 in 2010 and 57 in 2013.

The clinical parameters of the patients are shown in Table-II. There was no statistically significant difference between the two groups as regards demographic and clinical variables. Mean age of patients was52.29±13.44 in group I versus 53.47±12.97 in group II (overall=52.59±13.32). Out of the286 patients, 217(75.9%) were male and 69(24.1%) were female. BSA<1.8m^2 accounted for 21.3% (19.2% in Group Ivs27.8% in Group II) and BSA>1.8m^2 for 78.7% (80.8% in Group Ivs 72.7% in Group II). The two groups were statistically insignificant for risk factors, i.e diabetes, hypertension, peripheral vascular disease etc. (Table-II). All catheter related variables (Table-III) were statistically insignificant except the mode of insertion (p=0.005).

The incidence of complications (p=0.29) was 6.9% (Table-IV). Group I had a 6.1% complication rate vs 9.7% in Group II.

Vascular complications (p=0.42): Eight (2.8%) patients developed vascular complications. 5(2.3% in Group I) and 3(4.2% in Group II). Major vascular complications occurred in 5 patients, 3 in Group I and 2 Group II. Minor vascular complications occurred in 3 patients (Table IV).

Ischemic complications (p=0.99): Seven (2.4%) patients developed ischemic complications. 5(2.3% in Group I) and 2(2.8% in Group II). Major Ischemic Complications occurred in 3 patients (2 in Group I and 1 in Group II) Peripheral embolization requiring thrombo-embolectomy was the predominant major ischemic complication; one of these patients developed compartment syndrome and required fasciotomy and one required below knee amputation for ischemia. 4(3 in Group I and 1in Group II) patients developed Minor Ischemic Complications, which did not require any surgical intervention and were relieved by pulling out the catheter from the femoral artery.

Balloon catheter related complications (p=0.60): 5(1.75%) patients developed balloon catheter related complications 3(1.4% in Group I) and 2(2.9% in Group II). Infection at the site of insertion developed in 2 patients (1 in each group) which responded well to systemic antibiotics and local dressings. Rupture of the balloon occurred in 2 patients (both in Group I) requiring removal and insertion of the catheter into the contralateral side and Balloon entrapment during removal of a resterilized catheter in1 patient (in Group II) leading to retroperitoneal haemmorhage and death.

Year	No. of IABP	New	Re-Sterilized
2007	23(4.4%)	21	02
2008	28(5.1%)	24	04
2009	31 (6.27%)	25	06
2010	42 (8.50%)	31	11
2011	51(10.20%)	40	11
2012	54(10.8%)	37	17
2013	57(11.4%)	36	21

Table-I. Frequency of balloon application

Parameters	New IABP n=214	Re Sterilized IABP n=72	Total n=286	P-values
Age (Years)	52.29±13.44	53.47±12.97	**52.59±13.32**	0.12
Gender				
Male	166(77.6%)	51(70.8%)	**217(75.9%)**	0.25
Female	48(22.4%)	21(29.2%)	**69(24.1%)**	
Body Surface Area				
≥ 1.8m2	173(80.8%)	52(72.2%)	**225(78.7%)**	0.12
< 1.8 m^2	41(19.2%)	20(27.8%)	**61(21.3%)**	
Hypertension				
Yes	99(46.3%)	33(45.8%)	**132(46.2%)**	0.95
No	115(53.7%)	39(54.2%)	**154(53.8%)**	
Diabetes Mellitus				
Yes	102(47.7%)	37(51.4%)	**139(48.6%)**	0.58
No	112(52.3%)	35(48.6%)	**147(51.4%)**	
Hyperlipidemia				
Yes	79(36.9%)	30(41.7%)	**109(38.1%)**	0.47
No	135(63.1%)	42(58.3%)	**177(61.9%)**	
PVD				
Yes	16(7.5%)	9(12.5%)	**25(8.7%)**	0.13
No	198(92.5%)	63(87.5%)	**261(91.3%)**	
Smoking				
Yes	124(57.9%)	45(62.5%)	**169(59.1%)**	0.49
No	90(42.1%)	27(37.5%)	**117(40.9%)**	
Obesity				
Yes	46(21.5%)	16(22.2%)	**62(21.7%)**	0.89
No	168(78.5%)	56(77.8%)	**224(78.3%)**	
Family History				
Yes	66(30.8%)	26(36.1%)	**92(32.2%)**	0.41
No	148(69.2%)	46(63.9%)	**194(67.8%)**	

Table-II. Comparison of demographic parameter between groups

Parameters	New IABP n=214	Re Sterilized IABP n=72	Total n=286	P-values
Techniques of insertion				
Transaortic	1(0.5%)	1(1.4%)	2(0.7%)	0.14
Open femoral	7(3.3%)	6(8.3%)	13(4.5%)	
Percutaneous	206(96.3%)	65(90.3%)	271(94.8%)	
Mode of insertion				
Sheathless	149(69.6%)	32(44.4%)	181(63.3%)	0.005
With Sheath	65(30.4%)	40(55.6%)	105(36.7%)	
Size of Balloon				
Smaller (7F)	41(19.2%)	20(27.8%)	61(21.3%)	0.12
Large (8F)	173(80.8%)	52(72.2%)	225(78.7%)	
Volume of Balloon				
34cc	41(19.2%)	20(27.8%)	61(21.3%)	0.12
40cc	173(80.8%)	52(72.2%)	225(78.7%)	
Duration of IABP Therapy				
< 24 hrs	26(12.1%)	16(22.2%)	42(14.7%)	0.97
24 to 72 hrs	136(63.3%)	32(44.4%)	168(58.7%)	
72 to 168 hrs	49(22.9%)	22(30.6%)	71(24.8%)	
>168 hrs	3(1.4%)	2(2.8%)	5(1.7%)	

Table-III. Comparison of balloon related characteristic between groups

Morbidity / Mortality	New IABP n=214	Resterilized IABP n=72	P-Value
Overall Complication	**13(6.1%)**	**7(9.7%)**	**0.29**
Vascular Complication	**5(2.3%)**	**3(4.2%)**	
Major	3	2	
• Peripheral arterial injury	2	1	
• Exsanguinatinghaemorrhage	1	1	0.42
• False aneurysm	1	1	
Minor	2	1	
• Localized haematoma	2	1	
Ischemic Complication	**5(2.3%)**	**2(2.8%)**	
Major	2	1	0.99
• Peripheral embolization	2	1	
Minor	3	1	
Balloon Related Complications	**3(1.4%)**	**2(2.8%)**	
• Infection	1	1	0.60
• Rupture	2	0	
• Entrapment	0	1	
Mortality	**1(0.5%)**	**1(1.4%)**	0.44

Table-IV. Comparison of morbidity and mortality rate between groups

DISCUSSION

Coronary artery disease in Pakistan

For a nation with a poor economic status[16], essential health services are not easily accessible. GDP growth, relatively steady during the mid-2000s at a rate of 7%, slowed down during the economic crisis in 2008 and onwards to 4.7%, mainly attributable to a high inflation rate of 24.4% and lower savings rate. The average monthly income of Pakistanis is US$ 41 which is about Pak Rupees 3500. The population living below the poverty line is estimated to be between 23- 28% officially, but unofficial figures estimate this to be as high as 45%. This is reflected in the study, in which the application of the resterilized balloon has shown an increase during the course of the study. These factors are responsible for us using resterilized catheters in this group of patients in an emergency situation.

South East Asia has very high rates of Coronary Artery Disease (CAD); this disease predominantly effects the lower to middle socioeconomic stratum of Pakistani society.[14] CAD has become a major health problem in this country and is now the leading cause of death in the Indo-Pakistan subcontinent.[17]

CABG therefore accounts for the majority of cardiac surgeries (40-50%) performed at our institute. In recent years the disease pattern for Coronary Artery Disease has changed.[10,11,12] The increasing prevalence of risk factors like Hypertension, DM and unhealthy eating habits have reflected in patients presenting with diffuse disease and an increased incidence of myocardial infarctions leading to poor ventricular functions[18,19] thus resulting in an increased use of IABP.

Most patients who can afford the cost of surgery can also afford to buy a new IABP catheter which is available at subsidized rates at our institute. However, the majority (70-75%) of patients who present for surgery at our institute live below the poverty line and need full financial assistance to undergo surgery. This financial assistance is provided by the Social Welfare department to which an application for financial support has to be made. This process can take up to six weeks or longer. In this respect, the Social Welfare Department can only provide financial support for elective surgeries. Therefore IABP catheters when required in an emergency situation are not available. In these circumstances the use of resterilized IABP catheters is the only option left to us as a live-saving measure.

Single-Use Device (SUD) Reprocessing

The 1970s saw the start of the reuse of single-use medical devices.[20] Amongst the many concerns that arose were regulatory, ethical, medical, legal and economic issues; this has led to many controversies since the last few decades.[21] A document on single-use devices reprocessed by third parties or hospitals[22] was issued by the FDA in August 2000. It stated that similar regulations will be applicable to those hospitals or third-party reprocessors which are classified as manufacturers (Category II, IC). Premarket submission requirements have been put into place for devices and three (3) categories have been formed: within 6 months for class III devices (e.g, cardiovascular intra-aortic balloon pump, transluminal coronary angioplasty catheteretc); 12 months for class II devices (e.g, blood pressure cuff, bronchoscope biopsy forceps etc); and 18 months for class I devices (e.g, disposable medical scissors, ophthalmic knife etc).

Devices labeled for single use can in many circumstances be safely reprocessed and resterilized[23], provided it is done by a third party registered with and regulated by an authorized body, eg. the FDA. The third-party reprocessor should inspect, functionally test, clean, package, and sterilize such medical devices in such a manner that the safety and clinical effectiveness are maintained. Important considerations should also be given to the quality, physical characteristics, and performance of the device. The advantages are not only significant cost savings but also reduced amount of waste generated.

Many misconceptions[23] prevail about whether reuse of such devices put the patients at an additional risk. The Association of Medical Device Reprocesors (AMDR) clearifies several notions regarding single-use device reprocessing:

1. The manufacturer choses the “single use” label, primarily for economic reasons rather than patient safety concerns; it does not form part of FDA requirement.

2. The FDA’s adverse event database contra dictates the belief that reprocessed medical devices fail more often than original devices; there are over 6,500 reports of patient deaths associated with original (unreprocessed) devices since 2004 compared to 0 deaths as a result of the use of reprocessed devices.

3. It has to be ascertained that the device has been successfully cleaned, sterilized, and is functional, to the same, if not greater, degree as the original device before being commercially used, contradicting the myth that residues cannot be eliminated from reprocessed devices.

4. There are no legal, medical, or ethical issues as regards informed consent for the use of reprocessed devices as they are not investigational or experimental.

5. Reprocessing not only keeps a control on medical waste but also conserves money for hospitals so that they can redirect it in the appropriate direction i.e, hire more patient care staff, and improve technology.

The FDA has included IABPs[24] in a list of SUDs known to be Reprocessed or considered for Reprocessing:

1. Medical specialty=cardio
2. Device type=Intra-aortic balloon system
3. Regulation No=870.3535
4. Class= III
5. Product code=DSP
6. Risk =3(high risk)
7. Status=Critical
8. Premarket exemption= not subject to premarket notification requirements (no need for submission of validation data).

Ethylene Oxide (ETO) Sterilization

A highly flammable colorless gas(20), it is used in healthcare facilities to sterilize primarily critical items and occasionally semi-critical items that are moisture or heat sensitive; these items cannot be sterilized by steam without injurious effects. Stringent guidelines have been formulated highlighting acceptable ETO Sterilization limits ensuring that it poses minimal patient risk.

Complications

Complications can be classified as balloon related, vascular and ischaemic; reported incidence of 8 to 18%.[25-28] The mortality rate ranges from 0 to 2.6%. Various risk factors highlighted include patient related, eg, female sex, age, obesity, diabetes, hypertension, smoking, PVD, etc. and IABP related eg. Mode of insertion and duration of IABP therapy.[27, 29,30]

The use of a sheath for IABP insertion has been identified as a risk factor, as also highlighted by Meharwal[31] in an analysis of 911 cases, with the femoral artery size to the balloon size ratio strongly implicated in arterial occlusion. Thus, sheath less balloon insertion can therefore be expected to be associated with fewer complications. A study by Tatar et al.[28] has also reflected similar results.

LIMITATIONS

This was a retrospective study with its associated limitations. No local guidelines exist in Pakistan as regards the use of reprocessed Single Use Devices.

CONCLUSION

In this study, there was an insignificant statistical difference as regards demographic, clinical, balloon-related variables; similar results were reflected in the associated morbidity and mortality. This may emphasize the fact that resterilized balloons are just as effective and safe, if not more, as new IABPs. However, there is still a long way to go before making this a recommendation; further prospective randomized studies are required.

A multi-disciplinary committee is the need of the hour. It should be given the task of developing policies and practices relating to reuse, resterilization, and reprocessing of single use devices. The committee should include representatives from various disciplines of health care, in particular infection control, perioperative services, risk management, materials management and ethics to ascertain an efficient and infallible system. This has also been emphasized by American Society for Healthcare Central Service Professionals (ASHCSP).

ACKNOWLEDGMENTS/DISCLOSURES

None

REFERENCES

1. Pae WE, Pierce WS, Sapirstein JS. **Intra-aortic balloon counter pulsation, ventricular assist pumping and the artificial heart. I**n: Baue AE, Geha AS, Hammond GL, Laks H, Naunheim KS, Glenn WWL, editors. Glenn's thoracic and cardiovascular surgery. 6th ed. St. Lious Missouri: Appleton and Lange; 1996. p. 1825.

2. Moulopoulos SD, Topaz S, Kolff WJ. **Diastolic balloon pumping (with carbon dioxide) in the aorta: A mechanical assistance to the failing circulation.** Am Heart J 1962; 63:669–675.

3. Kantrowitz A, Tjonneland S, Freed PS, Phillips SJ, Butner AN, Sherman JL Jr. **Initial experience with intraaortic balloon pumping in cardiogenic shock.** JAMA 1968; 203:135-40.

4. Dar MI, Khan AB, Naqvi AJ. **Intra aortic balloon counter pulsation an improved outcome in high-risk patient for coronary artery bypass surgery: Intra-aortic Baloon Pump.** Pak Heart J 2005; 38(1-2):13-17.

5. Waksman R, Weiss AT, Gotsman MS, Hassin Y. **Intra-aortic balloon counter pulsation improves survival in cardiogenic shock complicating acute myocardial infarction.** Eur Heart J 1993; 14:71-4.

6. Christakis GT, Weisel RD, Fremes SE, etal. **Coronary artery bypass grafting in patients with poor ventricular function.** J Thorac Cardiovasc Surg 1992; 103:1083-92.

7. Ohman EM, George BS, Shite CJ. Et al. **Use of aortic counter pulsation to sustained coronary artery patency during acute myocardial infarction. Results of a randomized trial.** The randomized IABP study group. Circulation 1994; 90(2):792-9.

8. Maccioli GA, Lucas WJ, Norfleet EA. **Intraaortic balloon pump: A review.** J CardiothoracAnesth 1988; 2:365-7.

9. Santarpino G, Onorati F, Rubino AS, Abdalla K, Caroleo S, Santangelo E, et al. **Preoperative Intraaortic Balloon Pumping Improves Outcomes for High-Risk Patients in Routine Coronary Artery Bypass Graft Surgery.** Ann ThoracSurg 2009; 87:481-488.

10. Grover FL, Shroyer AL, Hammermeister K, et al. **A decade's experience with quality improvement in cardiac surgery using the Veterans Affairs and Society of Thoracic Surgeons national databases.** Ann Surg 2001; 234:464 –72.

11. Christenson JT, Simonet F, Badel P, et al. **Evaluation of**

preoperative intra-aortic balloon pump support in high risk coronary patients. Eur J CardiothoracSurg 1997; 11:1097–103.

12. Baskett RJ, Ghali WA, Maitland A, et al. **The intraaortic balloon pump in cardiac surgery.** Ann ThoracSurg 2002; 74:1276–87.

13. Iqbal MP. **Hyperhomocysteinemia and Coronary Artery Disease in Pakistan.** J Pak Med Assoc 2006; 56(6):282-5.

14. Samad A. **Coronary artery disease in Pakistan: Preventive aspects.** Pakistan J Cardiol 2003; 14:59-60.

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

16. **Wikipedia contributors.** Pakistan [document on the Internet]. San Francisco, CA: Wikipedia, the free encyclopedia; 2010 [updated 2010 Jul 16; cited 2010 Jul 17]. Available from: http://en.wikipedia.org/wiki/Pakistan.

17. Lopez AD, Mathers CD, Ezzati M, et al. **Global and regional burden of disease and risk factors, 2001: systematic analysis of population health data.** Lancet. 2006; 367:1747–5.

18. Saleheen D, Frossard 1? **CAD risk factors and acute myocardial infarction in Pakistan.** ActaCardiol 2004:59:417-24.

19. Samad A, Sahibzada WA, Nazir F, Khan AA, Mattu A, Menon N, et al. **Incidence of acute myocardial infarction.** Pakistan J Cardiol 1996; 7:13-7.

20. Rutala WA, Weber DJ, HICPAC. **Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention [document on the Internet].** Atlanta: National Center for Preparedness, Detection, and Control of Infectious Diseases; 2008 [updated 2009 Jun 03; cited 2010 July 17]Availablefrom:http://www.cdc.gov/ncidod/dhqp/sterile.html.

21. Greene VW. **Reuse of disposable devices. In: Mayhall CG, ed. Hospital Epidemiology and infection control.** 3rd ed. Philadelphia: Lippincott Williams & Wilkins; 1999. p.1201-8.

22. **Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.** FDA U.S. Food and Drug Administration [document on the Internet]. Maryland: Center for Devices and Radiological **Health; 2000 [updated 2010 Jun 05; cited 2010 Jul 17].** Available from:http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107164.htm.

23. **Single-Use Device Reprocessing.** Practice Green health [document on theInternet]. Virginia: Practice Green health; 2008 [cited 2010 Jul 17]. Available from:http://cms.h2e-online.org/ee/waste-reduction/waste-minimization/single-use-device-reprocessing/.

24. **Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data.** FDA U.S. Food and Drug Administration [document on the Internet]. Maryland: Department Of Health And Human Services, FDA; 2005 [updated 2009 Jun 25; cited 2010 Jul 17]. Available from:http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingleUseDevices/ucm121544.htm.

25. Naunheim KS, Swartz MT, Pennigton DG, Fiore AC, McBride LR, Peigh PS, Barnett MG, Vaca KJ, Kaiser GC, Willman VL. **Intra-aortic balloon pumping in patients requiring cardiac operations; risk analysis and long-term follow-up.** J Thorac Cardiovasc Surg 1992; 104:1654–1661.

26. Arafa EE, Pedersen TH, Svennevig JL, Fosse E, Geiran OR. **Intraaorticballoon pump in open heart operations: 10-year follow-up with risk analysis.** Ann ThoracSurg 1998; 65:741–747.

27. Gol MK, Bayazit M, Emir M, Tasdemir O, Bayazit K. **Vascular complications related to percutaneous insertion of intra-aortic balloon pump.** Ann ThoracSurg 1994; 58:1476–1480.

28. Tatar H, Cicek S, Demirkilic U, Ozal E, Suer H, Aslan M, Ozturk OY. **Vascular complications of intra-aortic balloon pumping: unsheathed versus sheathed insertion.** Ann ThoracSurg 1993; 55:1518–1521.

29. Barnett MG, Swartz MT, Peterson GJ, Naunheim KS, Pennington DG, Vaca KJ, Fiore AC, McBride LR, Peign P, Willman VL. **Vascular complications from intra-aortic balloons: Risk analysis.** J VascSurg 1994; 19:81–89.

30. Makhoul RG, Cole CW, McCann RL. **Vascular complications of intra-aortic Balloon pump: An analysis of 436 patients.** Am Surg 1993; 59:564–568.

31. Meharwal ZS, Trehan N. **Vascular complications of intra-aortic balloon.Insertion in patients undergoing coronary reavscularization: Analysis of 911 cases.** Eur J CardiothoracSurg 2002; 21:741-747.

If you light a lamp for someone else
it will also brighten your path.

– Buddha –

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Saad B. Zakai	Idea, Collection of data, Data analysis, Manuscript writing.	
2	Iqbal Hussain Pathan	Collection of data, Literature review, Drafting.	
3	Sohail K Bangash	Critical review.	
4	Tariq A. Siddiqi	Critical review.	
5	Fazle Rabbi	Critical review.	