

**EVALUATION OF THE USE AND EFFICACY OF INTRA-AORTIC BALLOON PUMP IN
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ABSTRACT

Background: The provision of specialized health care to patients undergoing cardiac surgery is based on the investigation and complete understanding of risk factors. During the perioperative period, the placement of an intra-aortic balloon pump (IABP) is quite common, both to support circulation through the increase of cardiac output and for the parallel action of cardio- and vasoactive drugs. **Aim & Methods:** The aim of the study was to investigate the use and efficacy of IABP in patients who had a heart surgery. Ninety eight patients of 3176 were chosen for this study and have been under IABP therapy perioperatively. These patients were assessed through report forms during their intensive care unit (ICU) stay about their medical history, admission details, blood tests results, surgery procedure, perioperative data. **Results:** Mean time duration of the IABP stay was 74 hours. It was used in patients of significantly older age with increased creatinine serum levels and decreased ejection fraction-EF ($p<0,001$). The use of IABP was higher in patients with recent myocardial infarction-MI ($n=45$), preoperative urgent need placement of the pump, redo surgeries and patients who presented different complications during operation ($p<0,001$). **Conclusions:** The use of the IABP was clearly needed in patients with myocardial infarction but as the study reveals, pump time, mortality rate, length of stay and complications were serious increased to these patients in general.

KEYWORDS: Intra-aortic balloon pump, CABG, mortality, cardiac surgery.**1. INTRODUCTION**

The idea of mechanical circulation support first appeared in the middle of the 20th century with the aim of reducing the energy requirements of the myocardium and helping it to continue its function. One of the devices that revolutionized this field is the Intra-Aortic Balloon Pump (IABP). Originally, the concept of counterpulsation was introduced in 1953 by Kantrowitz,^[1] who transferred blood from the femoral artery to the left coronary artery (via extracorporeal tube), with the use of experimental animals, increasing coronary perfusion.

In 1961, Clauss and colleagues,^[2] were the first to apply the counterpulsation technique to support the failing heart, using an extracorporeal pump (aspiration and

blood supply to the femoral arteries) and a year later, in 1962, Mouloupoulos and colleagues invented the IABP, consisting of an air chamber implanted in the descending aorta of experimental animals through the femoral artery.^[3]

In 1968, Kantrowitz announced the first clinical application of IABP. This pump was implanted in the descending aorta of two patients with cardiogenic shock, one of whom survived until discharge.^[4] Until 1980s, implantation and removal of IABP required two separate surgeries, which were accompanied by a high number of complications. However, in 1980, Bregman et al. reported successful and uncomplicated percutaneous IABP implantation (using the conventional Seldinger

technique) in 25 patients.^[5] Today, IABP is the most widely used temporary mechanical circulation assist device; it is estimated that approximately 200,000 IABPs are implanted annually in the United States alone.^[6]

The essential goal of the IABP therapy is to help the heart accomplish its function by increasing the oxygen supply to the myocardium while reducing the demands on it.^[7] The effect of IABP on circulatory hemodynamic support has been extensively studied, both experimentally and clinically.^[7-11] Several studies have found significant effects on aortic pressure, left ventricular pressure, pulse volume, ejection fraction, and cardiac output, left ventricular myocardial oxygen demand, coronary flow, and right ventricle. The IABP can be used both preoperatively and postoperatively. It is estimated that only in the US > 30% of patients undergoing complex heart surgery are temporarily assisted by IABP.^[12] Important ACC / AHA guidelines have been given for the use of IABP.

However, the long-term effectiveness of the IABP has not yet been clarified. Large multicenter studies including IABP SHOCK I and II indicated no significant difference between groups of patients [Cardiopulmonary Bypass Grafting (CABG) - Percutaneous Coronary Intervention (PCI)] in mortality in contrast to that of Litton and colleagues.^[13]

The Benchmark Counterpulsation Outcomes Registry,^[14] the largest IABP patient database in the US and non-US countries, described 22,663 cases of assistance, analyzing interesting facts such as the importance of effective pump placement timing, high-risk patients, and complications.

1.1. IABP and cardiac surgical patients

One of the indications for which IABP is often used is the hemodynamic support of cardiac surgical patients with low cardiac output syndrome not responding to inotropes.^[15] In addition, IABP has been used preoperatively (and intraoperatively) in patients with post-infarction mechanical complications or persistent unstable angina.^[16] More often, data coming from cardiac surgery patients indicate the effectiveness of preoperative IABP implantation. Preoperative implantation of the pump is associated with significantly lower in-hospital mortality.^[17,18] and significantly higher 10-year survival.^[19] compared to intraoperative or postoperative implantation. Mouloupoulos and colleagues strongly recommended the use of the pump in patients with myocardial infarction that affects the contractile function of the left ventricle, until surgical or non-surgical restoration. Berger,^[20] and Goldman,^[21] observed that the use of the IABP was the ultimate indication of postoperative heart failure. Patient groups in this category include:

- Postoperative left ventricular failure, unimproved directly after cardiac surgery.

- Patients who need reoperation (redo-CABG) while having left ventricular failure in unstable coronary syndrome.
- When the ejection fraction is lower than the end-diastolic pressure.
- Patients with severe aortic stenosis and affected EF.
- Patients with ischemic mitral valve insufficiency.
- Patients with left ventricular aneurysms and low EF.
- Patients with left strain disease and acute myocardial infarction.
- Postoperative right ventricular failure.^[22]

2. METHODS

2.1. Design and participants

The present study aimed to investigate the use frequency of IABP in cardiac surgical patients according to possible aggravating factors. 3176 patients were recorded with a mean age of 65.6 years who had undergone cardiac surgery at specific cardiac surgery center in Greece, during 2015-2020. 98 patients were finally included who met the criteria of IABP placement. A special registration form was designed for data collection which included demographic data such as age and gender, clinical information, length of stay in the ICU, IABP placement, previous medical history, underlying diseases, intraoperative data and complications. This form was completed by the ICU staff, upon the patient's entry into the intensive care department. In addition, the type of vasoactive drugs used postoperatively to achieve hemodynamic stability in patients was recorded. All patients included in the study were asked for written consent preoperatively, adhering to the principles of ethics regarding the processing of personal and medical data.

2.2. Statistical analysis

Mean values, standard deviations (SD) and median and interquartile range were used to describe the quantitative variables. Absolute (N) and relative (%) frequencies were used to describe the qualitative variables. Pearson's χ^2 test or Fisher's exact test was used to compare ratios where necessary. Student's t-test or the non-parametric Mann-Whitney criterion was used to compare quantitative variables between two groups. Significance levels were bilateral and the statistical significance was set at 0.05. The statistical program SPSS 22.0 was used for the analysis.

3. RESULTS

Data were recorded from 3176 heart surgery patients (78% male patients) with a mean age of 65.6 years (SD = 12yrs). Ninety eight had an IABP during hospital stay. Almost 45% of the total sample was diabetic, 43.7% were smokers and 20.4% had a recent heart attack. Most patients (52.0%) underwent CABG, while the rest underwent some other combined cardiac surgery (aortic aneurysm, CABG and/or valve replacement / repair, Bentall) and in 16% of them in total, as shown in *Table 1*, IABP was used with an average duration of use of 74

hours. The IABP was used in significantly older patients (mean age 69.4 years with SD = 10.1), while they showed higher preoperatively creatinine values and lower ejection fraction (EF (%), mean value 32.7 with

SD = 11.1). Also, the rate of use of the pump was significantly higher in patients with diabetes mellitus (4.1%).

Table 1: Demographic data according to registration form.

		IABP				P
		No		Yes		
		N	%	N	%	
Year	2015	559	96,9	18	3,1	0,464+
	2016	501	96,3	19	3,7	
	2017	589	98,2	11	1,8	
	2018	656	96,9	21	3,1	
	2019	735	96,3	28	3,7	
	2020	38	97,4	1	2,6	
Age, mean (SD)		65,6 (12)		69,43 (10,14)		<0,001‡
Gender	Males	2406	97,2	70	2,8	0,112+
	Females	671	96,0	28	4,0	
CABG	No	1487	97,4	39	2,6	0,097+
	Yes	1591	96,4	59	3,6	
Diabetes	No	1972	97,5	51	2,5	0,015+
	Yes	1106	95,9	47	4,1	
If yes, define treatment	DIET	128	97,0	4	3,0	0,775+
	IDDM	153	96,2	6	3,8	
	NIDDM	825	95,7	37	4,3	
Hypertension	No	577	96,3	22	3,7	0,356+
	Yes	2501	97,1	76	2,9	
Creatinine, mean (SD) median (IQR)		1,17 (1,05)	1 (0,8 – 1,2)	1,47 (2,29)	1,1 (0,9 – 1,4)	0,002‡‡
Smoking	No	1552	97,2	44	2,8	0,296+
	Yes	1339	96,4	50	3,6	
	Ex-smoker	187	97,9	4	2,1	
EF (%), mean (SD) median (IQR)		48,91 (8,87)		32,7 (11,1)		<0,001‡

⁺Pearson's χ^2 test ⁺⁺Fisher's exact test [‡]Student's t-test ^{‡‡}Mann-Whitney test

0.2% of patients had post-surgical complications associated with the IABP and more particularly 6.2% showed some kind of cardiovascular complication, 6.5% of the sample had hepatic complications and 3.2% died. The major complications associated with the use of IABP were postoperative bleeding, low platelet count and ischemia. In 12.2% of the patients with IABP, hemodynamic support was required with drug administration of inotropes and vasoconstrictors ($p < 0.093$) in high doses (22 – 80 ml / h) ($p < 0.034$). In 96.9% adrenaline was used as vasoconstrictor support and in 92.9% noradrenaline was the selected drug. The presence of the IABP was found to be generally associated with significantly higher adrenaline and noradrenaline administration frequency as well as significantly higher doses and longer dobutamine and dopamine support duration. Levosimendan was used in 13.3% of these patients, where it seemed to help significantly ($p < 0.001$). Also, the placement of the IABP was found to be associated with significantly longer time in extracorporeal circulation (Pump Time and Cross Clamp Time - CCT). Specifically, patients with a mean pump time of 149 minutes (SD = 55min) and CCT 95.5min (SD = 39min) were shown in the

present study to use more often the IABP. Furthermore, it was found that the average length of stay in the ICU of patients who used the pump (4 – 11days) differed significantly from patients who had not been placed in a support pump (1 – 2days) ($p < 0.001$). Also, there were higher rates of death (30 out of 68) and higher rates of complications compared to the control group (Table 2).

Table 2: IABP placement and complications.

	IABP				P	
	No		Yes			
	N	%	N	%		
PUMP Time (min), mean (SD) median (IQR)	122,09 (49,52)	114 (92 – 146)	149,05 (55,09)	137 (113 – 174)	<0,001‡‡	
CCT (min), mean (SD) median (IQR)	86,48 (39,51)	82 (62 – 106)	95,5 (39,11)	89 (69 – 110)	0,018‡‡	
ICU DAYS, mean (SD) median (IQR)	2,56 (9,97)	1 (1 – 2)	8,27 (6,49)	6 (4 – 11)	<0,001‡‡	
DCI	Alive	3005	97,6	68	69,4	<0,001++
	Death	73	2,4	30	30,6	
Vent.HRS, mean (SD) median (IQR)	18,24 (43,4)	12 (8 – 18)	108,72 (147,41)	58 (30 – 120)	<0,001‡‡	
ARRHYTHMIA	No	2696	87,6	50	51,0	<0,001+
	Yes	382	12,4	48	49,0	
COMP-IABP	No	3076	99,9	93	94,9	<0,001++
	Yes	2	0,1	5	5,1	
COMP-CARDIAC	No	2933	95,3	45	45,9	<0,001+
	Yes	145	4,7	53	54,1	
Simdax	No	3024	98,2	85	86,7	<0,001++
	Yes	54	1,8	13	13,3	
COMP-RENAL	No	2920	94,9	49	50,0	<0,001+
	Yes	158	5,1	49	50,0	

⁺Pearson's χ^2 test ⁺⁺Fisher's exact test ^{‡‡}Mann-Whitney test

The rates of IABP use were significantly higher postoperatively in patients with a recent MI or those who had the IABP inserted preoperatively or those who had been reoperated as well as in those with intraoperative

problems (Table 3). The IABP support was decreased gradually when the patient had a stable hemodynamic profile with a minimal dose of vasoconstrictor drugs and quite improved cardiac output (Cardiac Index > 2 lt/min).

Table 3: IABP rates of use postoperatively.

		IABP				P
		No		Yes		
		N	%	N	%	
RECENT MI	No	1299	98,9	14	1,1	<0,001+
	Yes	292	86,6	45	13,4	
PRE-IABP	No	1588	96,6	56	3,4	<0,001++
	Yes	2	40,0	3	60,0	
REDO	No	1569	96,7	53	3,3	<0,001++
	Yes	22	78,6	6	21,4	
Intraoperative complications	No	2887	99,2	23	0,8	<0,001+
	Yes	191	71,8	75	28,2	

⁺Pearson's χ^2 test ⁺⁺Fisher's exact test

4. DISCUSSION

In the current research, we aimed to evaluate and compare IABP application in different conditions of cardiovascular disease and especially in postoperative aspects, clinical features, timing, intensive care unit, hospital stays, and morbidity and mortality rates in patients who had required IABP support and undergone different cardiac surgeries.

Especially, in this study a large portion of patients who underwent cardiac surgery was included. More than half of the sample underwent a CABG surgery, while the rest underwent other combined cardiac surgeries. The intra-aortic balloon pump was placed in 6,2% of the reported cases.

As it was mentioned above, the intra-aortic balloon pump was mostly used in high-risk patients, with worse baseline values of serum creatinine levels or EF. Also, the placement of IABP was associated with higher dose of inotropic agents such as adrenaline, or levosimendan (13.3% compared to 1.8% of the control group). This implies that the use of IABP did not improve the hemodynamic condition of these patients as it was expected. In addition to that, there was noticed a prolongation of ventilation in the group of patients who received the IABP therapy (108 hrs compared to 18 hrs of the control group).

As it was observed, 5.1% of the patients had complications related to IABP placement. Also, half of these patients presented renal complications compared to

5.1% of the control group. This difference between the two groups of patients pointed out a higher morbidity rate in the group of patients to whom the IABP was placed. This fact indicates that other factors than the cardiac surgery might affect the condition of the patients that are already at high risk.

In this study it was shown, also, that in more than one out of ten patients that received IABP therapy, the IABP was not enough on its own. A strong inotropic agent was added to the treatment of the patients, aiming to ameliorate their short-term hemodynamic profile. However, a study that took place in 2012 by Lomivorotov,^[23] showed that the use of levosimendan on its own has a better effect on the patients' hemodynamic parameters compared to the combined use of both levosimendan and IABP. In our study, only 13 patients received levosimendan support and, consequently, further investigation has to be done due to its more frequent use in cardiac centers. These findings raise questions about whether the placement of IABP is a setback to the treatment of the patient.

Also, in our study, it was indicated that there is evidence regarding clinical outcomes of IABP in surgical patients such as mortality ($p < 0,001$) as it is confirmed by several studies that have shown efficacy of IABP in surgical mortality rate of patients. As previously described in the 1960s, IABPs had been applied in clinical practice as a cardiogenic shock therapy after MI and drug therapy-resistant unstable angina.^[24] Findings of a study performed in 2011, showed that IABP was associated with decrease in the mortality rates of patients with low cardiac output and severe myocardial ischemia in the preoperative period and, also, with avoidance of medically refractory arrhythmias in the postoperative period of patients in ICU.^[25] In another study in 2015, IABP was applied to recover low cardiac output, persistent angina pectoris, or arrhythmia in preoperative phase of the patients.^[26]

Furthermore, IABP is considered to be a very safe circulation support device. The Benchmark Registry reports an incidence of 2.6% for major complications related to IABP use (severe limb ischemia, severe bleeding, balloon leak, or death due to IABP insertion), and only 0.05% of in-hospital mortality was directly attributable to IABP.^[27] In our study, the IABP-related complications caused by IABP directly were very low.

Moreover, the surgical techniques may affect the early outcomes. Surgical techniques towards diffuse coronary disease include off-pump or on-pump CABG for myocardial revascularization, and open-CE (closed endarterectomy) or closed-CE for removing atherosclerotic plaques. A systematic review reported that no statistical difference in 30-day mortality was found between open-CE and closed-CE.^[28] Lee JH and colleagues also demonstrated that no statistical difference in operative mortality was found between the on-pump

CABG +CE and off-pump CABG+CE groups or between open-CE and closed-CE.^[29] However, we mainly focused on the patients with stable hemodynamic profile and those with intraoperative problems, as this factor plays a vital role on the use of inotropic drugs.

5. CONCLUSIONS

The use of IABP is undoubtedly a controversial issue. It supports heart function of cardiac surgical patients and as science evolves, new parameters appear to corroborate or restrict its placement. Clinicians must consider specific aggravating factors in clinical practice for pump selection in these patients in order to achieve a greater chance of a positive outcome in the course of the disease. In the field of research, there are many more that have to be done about the long-term efficacy of this device. In Greek cardiac surgical hospitals there is great need for prospective studies to be carried out as the use of pump is increased in ICUs.

6. Study limitations

Only a small sample size has been studied in this paper, thus it could affect the objectivity of the research results. Healthcare personnel's knowledge about IABP would be of great interest to be studied, though, in order to assess the need of training programs in Greece.

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