Intra-Aortic Balloon Counterpulsation in Acute Myocardial Infarction Complicated by Cardiogenic Shock

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Key words: *intra-aortic balloon counterpulsation; myocardial infarction; cardiogenic shock; percutaneous coronary intervention; complications.*

Summary. *Acute myocardial infarction complicated by cardiogenic shock is one of the main reasons of death in severely ill patients. One of the main indications for intra-aortic balloon counterpulsation is acute myocardial infarction complicated by cardiogenic shock. Aortic counterpulsation is associated with the risk of several important complications: bleeding, thrombosis, thrombocytopenia, limb ischemia, and aortic wall damage. The analysis of complications is necessary to better understand the course of myocardial infarction using aortic counterpulsation and to reduce the risk of complications.*

The aim of the study was to analyze the course of acute myocardial infarction complicated by cardiogenic shock in patients managed by intra-aortic balloon counterpulsation as well as to determine intra-aortic balloon counterpulsation-related complications.

Material and Methods. The course of acute myocardial infarction complicated by cardiogenic shock in patients with aortic counterpulsation was analyzed. Patients were recruited from the Cardiology Intensive Care Unit, Department of Cardiology, Lithuanian University of Health Sciences, during the period of 2004–2010. The study comprised 73 patients: 30 women (41.1%) and 43 men (58.9%).

Results. Atrial fibrillation and asystolia were the most common cardiac complications during counterpulsation. Atrioventricular block was the predominant disorder of cardiac conduction system; acute renal failure was the most common noncardiac complication. Complications such as major bleeding, infection, aortic wall damage, or amputations were not documented in our study. Successful percutaneous coronary intervention was associated with fewer complications and reduced mortality rate.

Conclusions. Aortic counterpulsation may be successfully employed providing significant hemodynamic support with rare major complications in a high-risk patient population. A unique finding of this study is a high rate of successful applications of aortic counterpulsation.

Introduction

Acute myocardial infarction (AMI) complicated by cardiogenic shock (CS) is the principal indication for intra-aortic balloon pump (IABP) or counterpulsation (1). CS causes cardiac mechanical inability to maintain adequate output. Patients with CS demonstrate clinical signs of low cardiac output and adequate intravascular volume (2). This mechanical cardiac-assist device significantly increases diastolic and mean blood pressure in the aorta and coronary arteries, while decreasing systolic pressure at the same time, thereby unloading the failing heart. By decreasing left ventricle afterload, IABP reduces left ventricle wall tension and oxygen demands (3, 4). Some studies demonstrated improved metabolic effects in the myocardium of patients with CS who

were treated with aortic counterpulsation (5). Admittedly, the efficiency of IABP is proven in many clinical scenarios such as high-risk percutaneous coronary interventions (PCI), unstable angina, CS, cardiac surgery, transplantation, and life-threatening arrhythmias (6). Multiple studies have suggested benefits of IABP in mortality of patients with CS-complicated AMI (4, 7–10).

AMI complicated by CS remains a leading cause of death in AMI patients, with a mortality rate as high as 60% to 70% (7, 11, 12). Previous literature reported the mortality rate of even 80%–90% using only pharmacological treatment (13–15). However, contemporary literature suggests that combination of thrombolysis, surgical, invasive procedures including IABP are associated with lower mortality

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rates. In the Global Utilisation of Streptokinase and TPA for Occluded Coronary Arteries (GUSTO-I) trial, the use IABP in patients undergoing reperfusion therapy led to a trend toward lower 30-day and 1-year mortality (4). In a report from the SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) Trial Registry, patients who underwent IABP had a significantly lower mortality rate, especially those who had received concomitant thrombolytic treatment. In particular, those who had received IABP placement and subsequently underwent revascularization with PCI or coronary artery bypass graft (CABG) surgery had dramatically lower in-hospital mortality: 39% vs. 78% (*P*<0.001) (8). Recently, the SHOCK trial showed that early revascularization with a high utilization of IABP led to a significant improvement in 6-month and 1-year mortality rates (16, 17). In 23 180 patients with CS in the National Registry of Myocardial Infarction 2 (NRMI-2), the use of IABP in conjunction with thrombolytic therapy decreased the odds of death by 18% (7). Analysis of the Benchmark Registry indicated that patients who received IABP in association with surgery or PCI had a lower in-hospital mortality compared with patients treated only medically (18.8% vs. 32.5%) (16).

Aortic counterpulsation has been associated with the risk of several important complications. Although the incidence of these complications is difficult to determine because of differing definitions, they are most likely decreasing as techniques, equipment, and experience improve (6).

Over the last several decades, there has been a dramatic improvement in technology and refinement in percutaneous insertion techniques. These advancements have lowered the incidence of major complications directly associated with IABP (6). Potential complications arising from the use of IABP include the following:

1. *Limb ischemia* may result from obstruction caused by the presence or improper position of the catheter.
2. *Aortic wall damage* may be caused by stripping of the endothelial surface, improper placement of the catheter, or unsuspected aortic wall disease.
3. *Thrombosis* can occur around the insertion site, on the aortic intima or the catheter, if it is left dormant in the aorta.
4. *Embolus formation* may occur from the beginning of insertion to the postremoval phase. Materials known to embolize include thrombi, plaque, gas, and air.
5. *Infection* may result when a debilitated patient is exposed to nosocomial organisms in the critical care setting.
6. *Thrombocytopenia* may be caused by the presence of the balloon, especially if the balloon to-

tally occludes the aorta during inflation.
7. *IAB rupture and/or entrapment.* If calcified plaque is present in the aorta around the area of the IAB, repeated contact with the plaque may cause a loss of IAB membrane integrity. This may result in blood in the catheter or clot in the IAB membrane if the exposure is prolonged. This may make IAB removal difficult. If blood is present or a leak is suspected, extreme caution must be exercised during IAB removal. Surgical removal should be considered.
8. *Bleeding* may occur at the IAB insertion site. If anticoagulation is given (increased activated clotting time or activated partial thromboplastin time), a higher risk of bleeding complications may be noted.

Early studies suggested that the most common vascular complication, limb ischemia, might occur in 14%–45% of patients receiving IABP therapy (18, 20). Contemporary large studies demonstrate considerably lower rates of complications: ischemia, 0.5%–5.6%; bleeding, 0.8%–4.6%; infection, 0.1%–0.5%; IABP-related death, 0.05%–0.5%; and IABP failure, 1.2%–2.8%. Studies reporting complication rates are diverse in terms of the indications for IABP, the technique used for insertion, the duration of use, and the specific definition of a complication (1, 19, 21–25).

Obviously, these rates of IABP-related complications are decreasing. However, the complication rate of myocardial infarction is increasing, making us consider how to improve the survival of patients with AMI complicated by CS. It is clear that previously the research of complications of such character was unnecessary because of high mortality. Therefore, the rates of these complications and the clinical course of myocardial infarction using IABP are unstudied.

The aim of the study was to analyze the course of acute myocardial infarction complicated by CS in patients managed by IABP as well as to determine IAB-related complications.

Material and Methods
The retrospective data analysis of patients who experienced AMI, complicated by CS, and were managed by IABP was carried out. All these patients were admitted within 12 hours from the onset of pain. Patients were selected for the investigation in the Cardiology Intensive Care Unit, Department of Cardiology, Lithuanian University of Health Sciences, during the period of 2006–2010. A total of 73 patients – 30 women (41.1%) and 43 men (58.9%) – were included into the study. The mean age was 70.5 years (SD, 2.8). The balloon was inserted under local anesthesia. The balloons ranged from 7.5 French (F) to 9.5 F. A total of 73 patients

underwent percutaneous balloon insertion with the "sheath-less technique" (26). Frequency and character of myocardial infarction–related complications were analyzed. Additionally, complications directly associated with IABP were studied. The success of revascularization was assessed according to the TIMI grade flow angiographic criteria. Angiographic success of revascularization was defined as an improvement in blood flow of coronary artery after revascularization comparing with blood flow grade before intervention.

Statistical analysis was performed by using software STATISTICA, version 8.0. Data are expressed as mean (SD). The Student t test was used for parametric samples. A value of $P<0.05$ was considered statistically significant. Stepwise logistic regression was performed to determine the independent correlates of in-hospital mortality, considering age, previous MI, performance of PCI, duration of counterpulsation in the model.

Results

The average duration from the onset of pain to hospitalization was 7.9 hours (SD, 6.8), while to counterpulsation 16.6 hours (SD, 18.3). The mean dose of inotropic support (dopamine) administered before the initiation of IABP was 10.4 μg·kg·min (SD, 5.1). The mean duration of counterpulsation was 76.9 hours (SD, 33.0).

The clinical conditions, which were observed before initiation of IABP, are shown in the Table 1. The most common noncardiac complications, associated with systemic influence of failing heart, and direct IABP-related complications are presented in Table 2.

In-hospital death occurred in 33 patients (45%) with IABP. The independent predictors of mortality in patients with AMI requiring IABP placement are shown in Table 3. The patients who experienced acute renal failure (ARF) were not older in comparison with patients whose renal function remained normal, and the mean duration of IABP application was not longer for patients suffering ARF (Fig.).

Table 1. Baseline Clinical Conditions

Clinical Conditions	No. of Patients	%
Cardiogenic shock	73	100
Anterior acute myocardial infarction	42	57.5
Pulmonary edema	36	49.3
Inferior acute myocardial infarction	31	42.5
Atrial fibrillation	20	27.4
Asystolia	19	26
Ventricular fibrillation	12	16.4
Atrioventricular block	10	13.7
Ventricular premature beats	8	11
Interventricular septal rupture	8	11
Right bundle-branch block	8	11
Ventricular tachycardia	7	9.6
Aneurysm of the left ventricle	6	8.2
3rd-degree atrioventricular block	4	5.5
Left bundle-branch block	3	4.1
2nd-degree atrioventricular block	3	4.1
Atrial flutter	2	2.7
1st-degree atrioventricular block	1	1.4

Primary PCI was successful in 47 patients (81%) and unsuccessful in 11 (19%). The positive impact of successful PCI was observed for some complications and mortality rate. Those who underwent successful revascularization with PCI had a lower mortality rate (16 [34%] vs. 9 [82%] patients, $P=0.003$) and lower rate of ARF (28% vs. 67%, $P=0.002$) in comparison with unsuccessful cases after intervention. Thirteen patients with multivessel disease and 2 patients after unsuccessful primary PCI were directed to surgical myocardial revascularization. Mortality rate after surgical revascularization was 53% (8 of the 15 patients), and it was higher comparing with primary PCI (43%). There was a trend toward the lower frequency of ventricular fibrillation in successfully revascularized patients (11% vs. 33%, $P>0.05$). Moreover, no femoral thrombosis in these patients was observed, whereas there were 2 cases of thrombosis in patients with unsuccessful PCI ($P=0.04$).

Femoral thrombosis was more commonly observed in patients with ventricular septal defect in comparison with patients with intact septum (25% vs. 0%,

Table 2. Complications of Intra-Aortic Balloon Pump and Failing Heart

Type of Complication	Clinical Condition	No. of Patients	%
Noncardiac complications	Acute Renal Failure	39	53.4
	Mental disorder	2	2.7
	Liver failure	1	1.4
Direct IABP-related complications	Thrombocytopenia	4	5.5
	Femoral thrombosis	2	2.7
	Poor inflation of balloon	1	1.4
	Severe bleeding	0	0
	Infection	0	0
	Aortic wall damage	0	0
	Amputation	0	0

IABP, intra-aortic balloon pump.

Table 3. Independent Factors of In-Hospital Mortality
by Logistic Regression Analysis

Factor	Multivariate Odds Ratio (95% CI)	*P* value
Duration of counterpulsation ⩽12 h	12.26 (2.27–21.28)	0.014
Previous myocardial infarction	4.68 (1.06–20.61)	0.042
Age >72 yrs	1.14 (1.139–1.288)	0.038
Performance of PCI	0.5 (0.41–0.59)	0.001

CI, confidence interval;
PCI, percutaneous coronary intervention.

Mean age, *P*=0.70
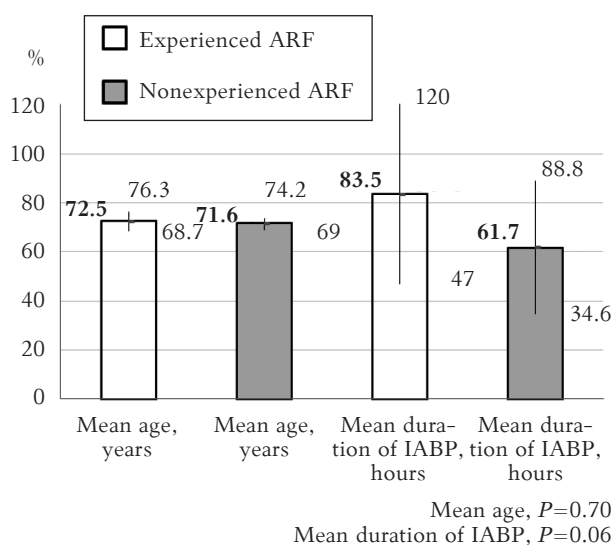Mean duration of IABP, *P*=0.06

Fig. Comparison of patients who experienced and did not
experience acute renal failure (ARF)

P<0.001). Moreover, the mean duration of counterpulsation was significantly longer in patients with femoral thrombosis (144 hours [SD, 0.53] vs. 70 hours [SD, 0.62], *P*=0.03). Complications such as bleeding, infection, aortic wall damage, or limb amputation were not registered in our study. Poor inflation of balloon was the cause of premature IABP removal for 1 patient (1.4%). A total of 35 patients were weaned from IABP, considering an improvement of their medical condition; however, 6 patients (8.2%) died later.

Discussion

The principal findings of this study were as follows: 1) the main clinical conditions, which were observed before initiation of IABP, were atrial fibrillation and asystolia; 2) the most common noncardiac complication was acute renal failure. ARF was not more frequent in older patients and in cases of longer IABP application; 3) the most common direct IABP-related complication was thrombocytopenia. It may occur with IABP because of the mechanical destruction of platelets and/or heparin

administration; 4) successful cases of PCI showed a lower mortality rate in comparison with unsuccessful cases; and 5) mental disorders were not observed.

Performance of IABP. The correct placement of an IABP results in notable augmentation of diastolic blood pressure with no change in heart rate. The Benchmark Registry reports that the mean duration of IABP application is 72 hours. Our study showed that the mean duration of counterpulsation was not much longer (76.9 hours [SD, 33.0]) as compared with that of the Benchmark Registry.

Mortality and Complications of IABP. The IABP Benchmark Registry (27) represents 5495 cases of myocardial infarction. This registry presents a statistical analysis of mortality in patients with AMI. Results show that overall mortality in patients with AMI complicated by CS was 30.7%. The IABP registry data were compared with the results of our study; the mortality rate (45%) in our study was higher than that in the IABP benchmark registry. Moreover, our investigators compared the data with the previous study, which was performed in 2006. The comparison revealed that the mortality rate of counterpulsated patients decreased by 20.25% during 4 years (2). A great improvement was achieved, because the insertion of IABP can be safely performed exclusively by trained medical professionals (28). Similarly, a recent single institution report showed a significant reduction in in-hospital mortality by 10%–20% during the last 5 years (29, 30). We would like to point out that IABP per se causes a low percentage of all complications that arise after the application of IABP. As shown in Table 2, the complications of IABP therapy occurred in 9.6% of patients. This figure is very similar to the published rates by most of the other studies (8.1%) (31). A unique finding of this study is a high rate of successful IABP applications: only in 1.4% of cases, IABP was not established due to poor inflation of balloon. The rate of femoral thrombosis in our study was 2.7% vs. 2.7% in the IABP benchmark registry. There is no doubt that cardiac pump failure due to coronary occlusion plays the main role in early systemic disorder. Moreover, the prolonged shock state induces the development of impaired organ perfusion. The results of our study confirmed this statement, because the most common noncardiac complication associated with systemic effect of failing heart was ARF. ARF was documented in 53.4% of all cases. IABP duration and patients' age were not related to a higher incidence of ARF. These findings show that the hemodynamic benefits of IABP may be achieved in high-risk patient group with relatively low risk (32, 33).

Use of Revascularization Procedures. The early revascularization strategy after IABP placement in patients with cardiogenic shock is a priority in most

centers. Revascularization was performed in more than 85% of AMI patients in the Department of Cardiology, Lithuanian University of Health Sciences. This study shows a positive effect of successful PCI on mortality rate. A considerable difference was seen between patients who received successful revascularization with PCI and unsuccessful cases. Successful cases had a lower mortality rate in comparison with unsuccessful cases (34% vs. 82%, $P=0.003$). Moreover, a lower rate of ARF after successful PCI was observed (28% vs. 67%, $P=0.002$). We suppose that this result is caused by improved hemodynamic and aborted development of impaired organ perfusion. Furthermore, we did not find any femoral thrombosis in these patients, whereas there was an 18.2% rate of thrombosis in patients with failed PCI ($P=0.005$), and similarly there was no difference in the mean duration of IABP in those patients. However, meta-analysis (34) shows that in patients treated with primary PCI, IABP was associated with a 6% increase (95% confidence interval, 3%–10%; $P<0.001$) in the 30-day mortality. This meta-analysis yielded unexpected results. Observational data do not support IABP therapy adjunctive to primary PCI. It suggests us to rethink our concept of adjunctive IABP therapy in patients with myocardial infarction complicated by CS after successful PCI. Organization of such a study has been initiated in Germany in 2010 (35).

Study Limitations. A limitation of this study, however, is that right heart catheterization was not routinely performed before and after IABP application. In addition, pulmonary capillary wedge pressure was not recorded. For this reason, we cannot evaluate if application of IABP resulted in preload reduction.

Conclusions

Intra-aortic balloon counterpulsation might be successfully employed providing significant hemodynamic support with rare major complications in a high-risk patient population. The highly successful percutaneous coronary intervention rates in patients managed with intra-aortic balloon counterpulsation decreased the mortality of patients with cardiogenic shock.

Statement of Conflicts of Interest
The authors state no conflict of interest.

Aortos kontrapulsacija esant kardiogeninio šoko komplikacijoms ūminio miokardo infarkto metu

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Raktažodžiai: intraaortinė kontrapulsacija, ūminis miokardo infarktas, kardiogeninis šokas, komplikacijos, perkutaninė vainikinių arterijų intervencija.

Santrauka. Ūminis miokardo infarktas, komplikavęsis kardiogeniniu šoku, yra viena dažniausių sunkių ligonių mirties priežasčių. Mokslinėje literatūroje nurodoma, kad intraaortinė kontrapulsacija pagerina ligonių, kurių būklė komplikavosi kardiogeniniu šoku, baigtis. Intraaortinė kontrapulsacija dažnai siejama su keliomis sunkiomis komplikacijomis: nukraujavimu, tromboze, trombocitopenija, galūnių išemija, aortos sienelės pažeidimu. Manome, kad mokslinis komplikacijų ištyrimas galėtų padėti suprasti ūminio miokardo infarkto eigą, intraaortinė kontrapulsacija leistų sumažinti komplikacijų atsiradimo riziką.

Tyrimo tikslas – ištirti ligonių, sergančių ūminiu miokardo infarktu ir patyrusių kardiogeninio šoko komplikacijas ir kuriems atlikta aortos kontrapulsacija, būklės pokyčius bei nustatyti komplikacijas, atsiradusias po aortos kontrapulsacijos.

Medžiaga ir metodai. Tyrimo metu buvo atlikta retrospektyvioji ligonių duomenų analizė. Į tyrimą įtraukti ligoniai gydyti Lietuvos sveikatos mokslų universiteto Kardiologijos intensyviosios terapijos skyriuje 2004–2010 metais. Tyrimo imtį sudarė 73 ligoniai: 30 (41,1 proc.) moterų ir 43 (58,9 proc.) vyrai. Visi ligoniai buvo patyrę miokardo infarktą, kuris komplikavosi kardiogeniniu šoku.

Rezultatai. Nustatėme, kad intraaortinės kontrapulsacijos metu dažniausiai pasitaikančios širdinės kilmės komplikacijos buvo prieširdžių virpėjimas ir asistolija. Dažniausiai pasitaikanti neširdinės kilmės komplikacija – ūminis inkstų nepakankamumas. Perkutaninių vainikinių arterijų intervencija (PVAI) sėkmingai atlikta 47 (81 proc.) ligoniams, nesėkmingai – 11 (19 proc.) ligonių. Buvo pastebėta teigiama PVAI įtaka ligonių baigtims. Ligoniams, kuriems atlikta PVAI, nustatytas mažesnis mirštamumo rodiklis lyginant su tais, kuriems procedūra nebuvo atlikta, atitinkamai – 33 proc. ir 83 proc., p=0,003. Tiems, kuriems procedūra nebuvo atlikta, taip pat rečiau užfiksuota ūminio inkstų nepakankamumo atvejų, atitinkamai – 28 proc. ir 67

proc., p=0,002. Tokių dėl intraaortinės kontrapulsacijos atsiradusių komplikacijų, kaip gausus kraujavimas, infekcija, aortos sienelės pažeidimas, galūnių amputacijos, tyrimo metu neužregistruota. Vidutinė kontrapulsacijos trukmė – 76,9±33,0 val.

Išvados. Šis tyrimas išskirtinis tuo, jog užfiksuotas didelis sėkmingų intraaortinės kontrapulsacijos atvejų skaičius. Ši procedūra gali būti sėkmingai atliekama sunkių ligonių hemodinamikai stabilizuoti esant minimaliam komplikacijų atsiradimo dažniui.

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