Indications, results of therapy and factors which influence survival in patients treated with intra-aortic balloon counterpulsation

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Abstract

Background and aim: During nearly 40 years of intraaortic balloon counterpulsation (IABP) application in advanced medical therapy more and more indications for this treatment have been proposed. Despite increasing experience with IABP, the clinical effects of IABP use are still unclear. The aim of this study was to determine results of IABP use and factors which influence survival in cardiogenic shock (CS) caused by different clinical disorders when treated with IABP.

Methods: 73 patients (mean age 58.3±12.6 years, 54 males) undergoing IABP were included in the study. Data were collected retrospectively. After analysis of the whole population a subgroup of patients admitted due to acute myocardial infarction (AMI) was evaluated. The in-hospital and overall mortality rates were assesed.

Results: In-hospital death occurred in 31 (42.5%) patients. Over half of these patients (n=17; 54.8%) died during first 7 days from admission. The main reason for IABP introduction was CS due to acute coronary syndrome (ACS) at admission in 62 (84.9%) patients. The in-hospital mortality in patients with AMI complicated by CS was 40.7%. The features which significantly influenced survival in patients with AMI were age – patients who died were older (64±8.9 vs. 58.6±9,1; p=0.0285), and ST segment changes – there was lower mortality rate in a subgroup with ST elevation AMI (18 vs. 6 patients, p=0.003). We also observed slightly higher incidence of anterior wall AMI in survivors than in non-survivors (p=0.06).

Conclusion: Our study presents several disorders which may be treated with IABP. Acute MI still remains the most frequent indication for IABP insertion. In the present study, AMI survivors and non-survivors, differed mainly in age, ST segment changes and infarction site. Non ST segment elevation AMI was associated with worse prognosis.

Key words: cardiogenic shock, intraaortic balloon pumping, myocardial infarction

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Background

Intra-aortic balloon counterpulsation (IABP) is widely used in a range of clinical settings in which cardiovascular dysfunction occurs. During nearly 40 years of IABP application in advanced medical therapy more and more indications have been proposed [1-3]. Despite increasing experience with IABP, the clinical effects of IABP use are still unclear. Most studies evaluate patients' survival in cardiogenic shock (CS) complicating acute myocardial infarction (AMI) [4-7]. The aim of this study was to determine results of IABP use and factors which influence survival in CS caused by different clinical disorders and treated with IABP.

Methods

Data collection

Patients undergoing IABP from April 1996 to September 2006 in our department were included in the study. Data were collected retrospectively. The following information was particularly sought: demographic and clinical data, treatment, complications and survival. Patients included in the study were treated with IABP because of acute indications and diagnosis of CS. One patient developed signs and symptoms of anaphylactic shock after coronarography. The IABP use before and after coronary artery bypass surgery in high-risk patients without signs of CS (preventive application) was an exclusion criterion.

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Definitions

Cardiogenic shock was diagnosed when peripheral hypoperfusion with marked and persistent hypotension (systolic arterial pressure less than 90 mmHg or a drop of mean arterial pressure >30 mmHg) and/or low urine output (less than 0.5 ml/kg/h) with a pulse rate >60 bmp with or without evidence of organ congestion were observed.

Insertion technique

The IABP balloon was inserted under fluoroscopic visualisation in the catheterisation laboratory by cardiologists experienced in the femoral artery catheterisation technique using the Seldinger technique. The intra-aortic balloon catheter was induced through the sheath and positioned in the thoracic descending aorta just below the origin of the left subclavian artery. Counterpulsation was begun and the timing of balloon inflation and deflation was optimised. Each patient received a heparin bolus and was then given a continuous heparin infusion titrated to a partial thromboplastin time of 1.5 to 2 × control. The balloon catheter was removed percutaneously, and manual compression was applied until haemostasis was achieved. The decision of balloon removal was made after clinical improvement or when major complications occurred.

Pharmacological treatment

Pharmacological treatment varied in patients depending on their clinical status, but basic medications were administered following current medical knowledge. In all patients catecholamines were used and time of treatment depended on the clinical manifestation.

Follow-up

Follow-up was obtained by patient, family or statistical office interview. The mean follow-up was 744±980 days (range 1-3969 days).

Statistical analysis

Data are reported as mean± standard deviation (x ± SD) or percentage. The data analyses were performed using CSS STATISTICA for Windows, release 7.1. Comparisons between groups were performed by unpaired t-test and Fisher's exact test as indicated. Statistical significance was considered when p value was <0.05. The variables with statistical significance in univariate analysis were included in a multivariate analysis, which was then conducted using the Cox proportional hazard model. Survival curves were computed with the Kaplan-Meier method.

Results

73 patients (mean age 58.3±12.6, 54 males) admitted directly to our department were treated with application of IABP. The mean duration of hospitalisation was 18.1±14.9 days (range 1 to 78 days). In-hospital death occurred in 31 (42.5%) patients. The in-hospital survival curve is presented in Figure 1. Over half of patients who did not survive died during the first seven days after admission (n=17; 54.8%). Fourteen patients died during follow-up (Figure 2). The indications for IABP insertion are summarised in Table I. The main reason for IABP introduction to the treatment was CS due to acute coronary syndrome (ACS) at admission in 62 patients (84.9%) . One patient developed signs and symptoms of anaphylactic shock after coronary angiography. Because of severe arterial hypotension and poor response to medical therapy, IABP was introduced. On the basis of in-hospital survival the study group was divided into two subgroups – survivors (n=42) and non-survivors (n=31). The clinical and demographic data are presented in Table II.

Analysis of patients admitted due to AMI was also performed. The results are presented in Table III.

In multivariate analysis for in-hospital phase, ST segment changes (p=0.005; HR=4.09; 95% CI 1.52-11.0)

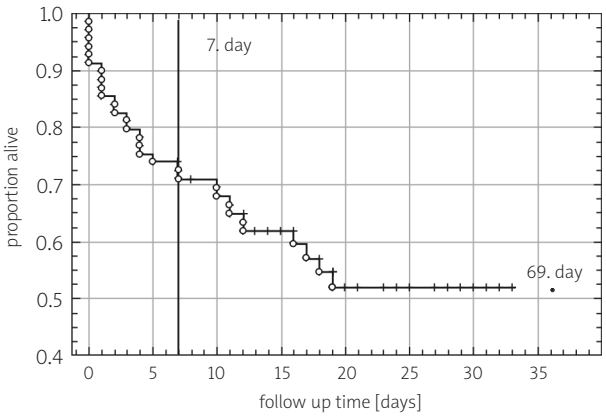

Figure 1. Kaplan-Meier survival curve for 73 patients with cardiogenic shock treated with inraaortic balloon pump during hospitalisation. In--hospital observation

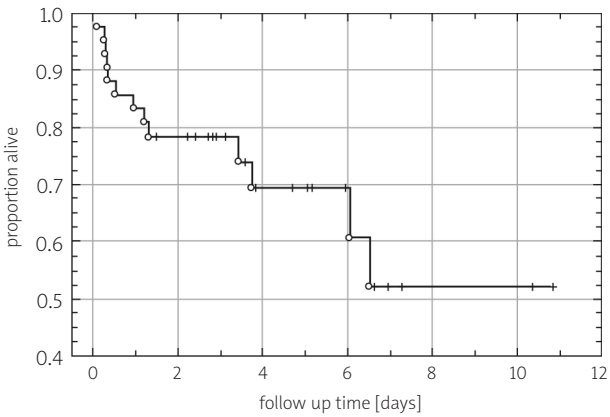

Figure 2. Kaplan-Meier survival curve for 42 patients after the discharge from the hospital during long-term follow up. Late morality

Table I. Indications for IABP insertion and mortality rate in each group

Indication	n=73	Mortality
Cardiogenic shock complicating AMI or unstable angina	56 (76.7%)	24 (32.9%)
Mechanical complications of AMI (ventricular septal defect)	6 (8.2%)	2 (2.7%)
Complications of coronary angiography and/or angioplasty (AMI or anaphylactic shock)	4 (5.5%)	1 (1.4%)
Decompensation of heart failure (due to ischaemia or dilated cardiomyopathy)	5 (6.8%)	3 (4.1%)
Decompensated aortic stenosis	1 (1.4%)	1 (1.4%)
Cardiogenic shock in acute myocarditis	1 (1.4%)	0

Table II. Demographic and clinical data

	Non-survivors (n=31)	Survivors (n=42)	p
Male	24 (77.4%)	30 (71.4%)	NS
Age [years]	61.1±12.6	56.3±12.3	NS
History of AP	17 (54.8%)	21 (50%)	NS
History of MI	14 (45.2%)	16 (38.1%)	NS
History of PCI/CABG	5 (16.1%)	9 (21.4%)	NS
Hypertension	16 (51.6%)	21 (50%)	NS
Diabetes	10 (32.3%)	9 (21.4%)	NS
CS at admission	19 (61.3%)	21 (50%)	NS
Acute MI	24 (77.4%)	35 (83.3%)	NS
Fibrinolysis	6 (19.4%)	10 (23.8%)	NS
Mean IABP time [days]	4.2±4.4	4.7±4.5	NS
Mean CA time [days]	6.3±8.1	5.87±5.2	NS

Abbreviations: MI – myocardial infarction, PCI – percutaneous coronary intervention, CABG – coronary artery bypass grafting, CS – cardiogenic shock, CA – catecholamines, AP – angina pectoris

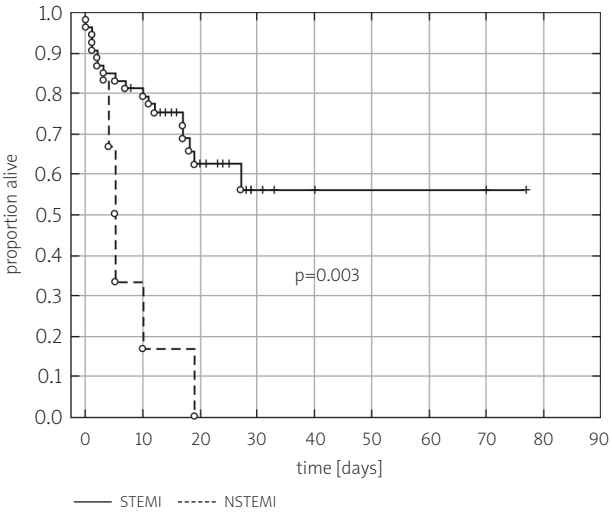

Figure 3. Kaplan-Meier survival curve in patients categorized into ST segment elevation MI (STEMI) and no segment elevation MI (NSTEMI)

and in long-term observation, age (p=0.008; HR=1.05; 95% CI 1.01-1.09) and ST segment changes (p=0.0005; HR=5.71; 95 %CI 2.12-15.4) were independent factors associated with mortality.

Since all patients with non-ST segment elevation MI (NSTEMI) died, we also analysed patients according to ST segment changes. The results of this analysis are presented in Table IV and survival curves in Figure 3.

Discussion

Our study examined indications for IABP use, results of treatment and factors which influence patient's survival. The IABP was used for a variety of disorders complicated with CS; however, ACS was the most frequent indication. Although some authors suggest the use of IABP in patients with AMI without hypotension and during primary percutaneous coronary intervention (PCI) [8-11], this is not the case in our department. In the PAMI-II trial [7], which was performed to determine the role of prophylactic IABP after primary PCI in AMI, the IABP strategy conferred modest benefits in reduction of recurrent ischaemia (p=0.08) and subsequent unscheduled repeated catheterisations, but did not reduce the rate of infarct-related artery reocclusion, reinfarction or mortality, and was associated with a higher incidence of stroke. Also van't Hof et al. [12] failed to document a significant role of IABP in uncomplicated MI. According to their results, systematic use of IABP after primary PCI does not lead to myocardial salvage or to a better clinical outcome in high-risk patients with MI; thus, the use of IABP after primary PCI for MI should be reserved for patients with severe haemodynamic compromise. Stone et al. [13] revealed that placement of an IABP resulted in notable augmentation of diastolic blood pressure and a significant, though small, reduction in systolic blood pressure, with no change in heart rate. These findings suggest that the major haemodynamic and clinical benefits of IABP could be achieved in patients with systemic hypotension, with relatively little reduction in afterload or myocardial oxygen demand. In our department IABP is introduced in the situation of acute indications.

In our study the mortality rate varied greatly between the groups with various underlying diseases. However, subgroups were not comparable due to the different numbers of patients. The overall mortality in patients with MI complicated by CS, including MI with ventricular

Table III. Comparison of demographic and clinical characteristics as well as the outcome between survivors and non-survivors of myocardial infarction

	In-hospital observation			Long-term follow-up		
	Non-survivors (n=24)	Survivors (n=35)	p	Non-survivors (n=35)	Survivors (n=24)	p
Male	17 (70.8%)	24 (68.6%)	NS	24 (68.6%)	17 (70.8%)	NS
Age [years]	64 ± 8.9	58.6± 9.1	0.03	63.5±8.4	56.9±10	0.007
History of AP	14(58.3%)	16 (45.7%)	NS	20 (57.1%)	10 (41.7%)	NS
History of MI	11 (45.8%)	11 (31.4%)	NS	16 (45.7%)	6 (25%)	NS
History of PCI/CABG	3 (12.5%)	6 (17.1%)	NS	4 (11.4%)	5 (20.8%)	NS
Arterial hypertension	13 (54.2%)	17 (48.6%)	NS	15 (42.8%)	15 (62.5%)	NS
Diabetes	9 (37.5 %)	6 (17.1%)	NS	10 (28.5%)	5 (20.8%)	NS
COPD	3 (12.5%)	5 (14.3%)	NS	6 (17.1%)	2 (8.3%)	NS
ST elevation MI	18 (75%)	35 (100%)	0.003	29 (82.9%)	24 (100%)	0.07
Anterior MI	11 (45.8%)	25 (71.4%)	0.06	19 (54.3%)	17 (70.8%)	NS
Triple-vessel disease	10 (41.7%)	8 (22.9%)	NS	12 (34.3%)	6 (25%)	NS
Left main disease	6 (25%)	5 (14.3%)	NS	8 (22.9%)	3 (12.5%)	NS
SBP at admission [mmHg]	102.0±22	103.9±28.3	NS	97.5±28.6	111.5±27.6	NS
HR at admission [bpm]	99.5±22	96.9±23	NS	99.8±21.8	96.4±23.4	NS
LV diameter [mm]	55.9±6.1	53.2±8.7	NS	55.3±7.7	52.4±10	NS
EF [%]	32.3±18	35.1±15.1	NS	33.7±18	35±13.8	NS
CK max [U/l]	3286.1±4084.2	3139.1±2832.3	NS	3063±3604.8	3359.8±2941	NS
Creatinine [μmol/l]	144.1±96.7	151.7±107.7	NS	141.5±87.6	147.8±110	NS
Baseline platelets count [× 10^3/ml]	211.3±77.7	268.9±109.9	0.05	225.6±102.4	276.5±98.2	0.08
Limb ischaemia	2 (8.3%)	3 (8.6%)	NS	2 (5.7%)	3 (12.5%)	NS

Abbreviations: EF – ejection fraction, CK – creatine kinase, SBP – systolic blood pressure, HR – heart rate, COPD – chronic obstructive pulmonary disease. Rest of abbreviations: as in Table II

septal rupture, was 40.7%. Patients who died were older (p=0.03). We observed slightly higher incidence of anterior wall MI in survivors than in non-survivors (p=0.06). The difference in mortality did not reach statistical significance, but these results may suggest a worse prognosis in patients with inferior wall MI, even despite aggressive treatment including IABP. The overall haemodynamic benefits of IABP are a reduction in left ventricular wall stress from decreased filling pressures (thus, a decrease in myocardial oxygen demand) and decreased afterload, which improves stroke volume and cardiac output. We suggest that patients with inferior wall MI, which is often accompanied by the right ventricular infarction, may not benefit from IABP as much as patients with anterior MI.

We also observed the difference in the ST segment changes between AMI survivors and non-survivors. All patients with NSTEMI died. We analysed this group of patients and found out that these patients had triple vessel disease more often (p=0.008), and had already been diagnosed with angina pectoris before current hospitalisation (p=0.02). They also tended to have hypertension, diabetes and a history of previous MI. However, these differences were not significant, probably because of the small number of patients with NSTEMI.

Among the group with ACS we observed CS in 4 patients after elective PCI with a subsequent need for IABP use. In all these patients there was a history of coronary artery disease, a history of MI and coronary artery disease risk factors. One patient developed anaphylactic shock with no response to traditional treatment. In similar situations Mishra et al. [14] suggested prophylactic use of IABP (P-IABP) in patients with high-risk PCI. The procedural success was higher in the P-IABP group, with lower in-hospital mortality and major complications, than in the R-IABP group (rescue IABP). At 6 months, the mortality and major adverse cardiac event rates were lower in the P-IABP group. The incidence of vascular complications was low and comparable except for more major bleeding. As mentioned before, we do not use IABP as a prophylactic procedure. However, this proposal may be taken into consideration some groups of patients.

The mean duration of IABP insertion was 4.6±4.4 days. The decision of balloon removal was made after clinical improvement or due to the occurrence of major

Table IV. Patients with MI – divided into subgroups with ST and non-ST elevation MI

	NSTEMI (n=6)	STEMI (n=53)	P
Death	6 (100%)	18 (34%)	0.003
Male	4 (66.7%)	37 (69.8%)	NS
Age [years]	62.7±6.3	60.6±9.7	NS
History of MI	4 (66.7%)	18 (34%)	NS
History of PTCA/CABG	1 (16.7%)	8 (15.1%)	NS
Hypertension	4 (66.7%)	26 (49.1%)	NS
Diabetes	3 (50%)	12 (22.6%)	NS
AP	6 (100%)	24 (45.3%)	0.02
Anterior MI	2 (33.3%)	34 (64.2%)	NS
Rescue PCI	2 (33.3%)	14 (26.4%)	NS
SBP at admission [mmHg]	98.3±40.1	103.7±27.6	NS
HR [bpm]	104.2±26.7	97.8±22	NS
CK max [U/l]	4022.7±3785.1	3090.9±3271.3	NS
Baseline platelets count [× 10^3/ml]	230.3±28.3	251.0±108.9	NS
LV diameter [mm]	57.8±6.2	53.5±8.3	NS
EF [%]	27.5±20.2	35.2±15.2	NS
Triple vessel disease	5 (83.3 %)	13 (24.5 %)	0.008
AMI complicated with VSD	0 (0 %)	6 (11.3 %)	NS
Hospitalisation [days]	8.7±6.1	18.8±14.6	NS

Abbreviations: see Tables II and III

complications. Li et al. [15] divided patients who had criteria for IABP withdrawal into two subgroups – in the control group IABP was removed, whereas the study group continued IABP for additional seven days. The authors suggested that prolonged use of IABP for up to 10 days may even offer additional long-term benefits in LV function and exercise tolerance. Our subgroups (survivors and non-survivors) did not differ much in mean duration of IABP. Only 10 patients had an IABP inserted for at least ten days. Among them, 4 patients died during hospitalisation and 4 deaths were observed in follow-up after discharge. In these patients prolonged use of IABP was related to worse course and adverse early and late prognosis.

Conclusions

Our study presents several disorders complicated with CS which may be treated with IABP. Myocardial infarction still remains the most frequent indication for IABP insertion. In the present study, among patients with MI treated with IABP, lower mortality was observed in younger patients, those with anterior location of MI and those with STEMI. The NSTEMI patients had worse prognosis, mainly because of the presence of more cardiovascular risk factors.

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Wskazania, wyniki terapii i czynniki wpływające na przeżycie u chorych leczonych kontrapulsacją wewnątrzaortalną

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Streszczenie

Wstęp: Kontrapulsacja wewnątrzaortalna (IABP), jako metoda doraźnego leczenia podtrzymującego u chorych wymagających mechanicznego wspomagania krążenia, została zaproponowana po raz pierwszy przez Moulopoulosa i wsp. w 1961 r. W ciągu następnych 40 lat wykorzystywania w praktyce klinicznej wskazania do zastosowania IABP znacznie się rozszerzyły, głównie dzięki stosunkowo prostej obsłudze i skuteczności hemodynamicznej. Jednak pomimo rozpowszechnienia tej metody i dużego doświadczenia, efekty kliniczne jej zastosowania są wciąż niejasne, a śmiertelność chorych ze wstrząsem kardiogennym jest nadal duża.

Cel: Ocena rezultatów stosowania IABP oraz czynników, które mogą w istotny sposób wpływać na przeżycie chorych ze wstrząsem kardiogennym o różnej etiologii leczonym IABP.

Materiał i metody: Do badania włączono 73 chorych leczonych w naszym ośrodku z powodu wstrząsu kardiogennego o różnej etiologii z zastosowaniem IABP w latach 1996–2006. Dane analizowano retrospektywnie. Szczególną uwagę zwrócono na wskazania do założenia IABP, czynniki demograficzne i kliniczne, metody terapeutyczne – farmakoterapię i leczenie inwazyjne, ewentualne powikłania oraz śmiertelność – wewnątrzszpitalną i w obserwacji odległej. Z badania wykluczono chorych, u których IABP stosowana była profilaktycznie przed lub po operacji kardiochirurgicznej.

Wyniki: Najczęstszym wskazaniem do założenia IABP w badanej grupie był wstrząs kardiogenny w przebiegu ostrego zespołu wieńcowego (ostry zawał serca z uniesieniem lub bez uniesienia odcinka ST oraz dławica piersiowa niestabilna) – u 84,9% chorych (n=62). W czasie hospitalizacji zmarło 31 chorych (42,5%), ponad połowa z nich (n=17; 54,8%) w ciągu pierwszych 7 dób od przyjęcia. Ocenie poddano czynniki, które mogły wpłynąć na przeżywalność chorych ze wstrząsem niezależnie od jego przyczyny, jednak nie uzyskano wyników w sposób istotny różnicujących chorych. Po analizie całej grupy wyodrębniono 59 chorych przyjętych z powodu ostrego zawału serca powikłanego wstrząsem kardiogennym. Ze względu na wysoką śmiertelność wśród chorych z zawałem serca bez uniesienia odcinka ST, porównano również czynniki demograficzne i kliniczne w zależności od ostrego niedokrwienia z uniesieniem i bez uniesienia odcinka ST. Śmiertelność wewnątrzszpitalna wśród chorych z ostrym zawałem serca powikłanym wstrząsem kardiogennym wyniosła 40,7%. Do czynników, które w istotny sposób wpłynęły na przeżycie, należały wiek – odnotowano wyższą śmiertelność u starszych chorych (64±8,9 *vs* 58,6±9,1, p=0,0285), oraz zmiany odcinka ST, przy czym zaobserwowano zaskakująco niższą śmiertelność w podgrupie chorych z ostrym zawałem serca z uniesieniem odcinka ST (18 *vs* 6 chorych, p=0,003). Stwierdziliśmy również nieco częstsze występowanie zawału serca ściany przedniej w grupie chorych, którzy przeżyli, niż w grupie chorych, którzy zmarli (p=0,06).

Wnioski: Nasze badanie prezentuje szereg schorzeń kardiologicznych, które – powikłane wstrząsem kardiogennym – mogą być leczone przy użyciu IABP. Ostry zawał serca jest jednak nadal podstawowym wskazaniem do zastosowania tej metody. Z naszej analizy wynika, że czynnikami niekorzystnie wpływającymi na rokowanie chorych z ostrym zawałem serca powikłanym wstrząsem kardiogennym leczonych IABP są: wiek, zawał serca bez uniesienia odcinka ST oraz lokalizacja dolna zawału serca.

Słowa kluczowe: wstrząs kardiogenny, kontrapulsacja wewnątrzaortalna, zawał serca

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