Effects of Intra-Aortic Balloon Counterpulsation Pump on Mortality of Acute Myocardial Infarction



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Abstract

Background: Several randomized controlled trials (RCTs) have evaluated the effect of intra-aortic balloon counterpulsation pump(IABP) on the mortality of acute myocardial infarction (AMI).

Objectives: To analyze the relevant RCT data on the effect of IABP on mortality and the occurrence of bleeding in AMI.

Data Sources: Published RCTs on the treatment of AMI by IABP were retrieved in searches of Medline, EMBASE, Cochrane and other related databases. The last search was conducted on July 20, 2014.

Study Eligibility Criteria: Randomized clinical trials comparing IABP to controls as treatment for AMI.

Participants: Patients with AMI.

Synthesis Methods: The primary endpoint was mortality, and the secondary endpoint was bleeding events. To account for to heterogeneity, a random-effects model was used to analyze the study data.

Results: Ten trials with a total population of 973 patients that were included in the analysis showed no significant difference in 2-month mortality between the IABP and the control groups. The 6-month mortality in the IABP group was not significantly lower than in the control group in the four RCTs that enrolled 59 AMI patients with CS. But in the four that enrolled AMI 66 patients without CS, the data showed opposite conclusion.

Conclusions: IABP cannot reduce within 2 months and 6–12 months mortality of AMI patients with CS as well as within 2 months mortality of AMI patients without CS, but can reduce 6–12 months mortality of AMI patients without CS. In addition, IABP can increase the risk of bleeding.

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 \P LY and MZ are co-first authors on this work.

Introduction

Intra-aortic balloon counterpulsation pump(IABP) can increase blood flow in the coronary artery and the brain while reducing afterload and cardiac oxygen consumption [1]. Kantrowitz [2] first reported the clinical application of IABP. Because IABP can quickly improve the effect of patients' clinical symptom, so this technology causes people's attention. Although numerous percutaneous circulation support equipments are applied, the effect of IABP in adjuvant therapy of AMI patients is still controversial. Some previous studies show that IABP benefits for high-risk patients with AMI, but most of these studies are non-randomized and retrospective, with serious selection bias and poor credibility. However, in some other studies, the effectiveness of IABP in adjuvant therapy for severe patients with AMI has not been ensured [14,18]. The American College of Cardiology and American Heart Association (ACC/AHA) guidelines recommend IABP for patients with unstable angina and non-ST-elevation myocardial infarction UA/NSTEMI with severe ischemia [3]. However, the curative effect of IABP as a treatment of AMI is still unresolved, and it is not clear whether time and cardiogenic shock (CS) influence its effectiveness. To evaluate the curative effect systematically, we performed a meta-analysis of randomized controlled trials (RCTs) on the treatment of AMI by IABP.

Methods

1. Data sources and search strategy

the The Medline, EMBASE, Cochrane databases, and related websites were searched without restriction by publication date or publication status; however, only articles published in English were selected. The search keywords included intra-aortic balloon counterpulsation, intra-aortic balloon pump, percutaneous coronary intervention, acute coronary syndrome, acute myocardial infarction, IABP, IABC, PCI, and ACS. The last search was conducted on July 20, 2014.

2. Selection criteria

To ensure the quality of the meta-analysis, the following selection and exclusion criteria were applied to assess the RCTs that were retrieved during the searches. Only published RCTs that enrolled AMI patients treated with drugs or PCI (percutaneous coronary intervention) were eligible. Only studies of IABP as an intervention for circulatory support were included, and only if the methods, study dates, sample size, and results were clearly and completely described. Trials that were non- or incompletely randomized, that included patients with coronary syndromes other than AMI, or patients treated with coronary artery bypass grafting, that compared IABP with other percutaneous circulation support equipment, or with unclear data reporting were excluded.

3. Data extraction and management

In the selected articles, all-cause mortality was the primary endpoint used to assess the curative effect of IABP on AMI. Bleeding was a secondary endpoint used to assess IABP safety. The patients in the selected RCTs were divided into subgroups whether with or without CS to account for treatment effects depending on the patients' condition. Mortality was evaluated in two subgroups depending on follow-up duration: mortality within 2 months (i.e., in-hospital, at 1 month, and at 2 months), and mortality within 6–12 months.

4. Methodology/quality assessment

The RCT quality was assessed independently by two reviewers. The 12 RCTs that were selected were assessed using the Cochrane Collaboration bias risk tool, which considers the following six criteria: proper random sequence generation, concealment of subjects' group allocation, blinding during outcomes assessment, complete recording and reporting of outcomes data, and lack of experimental bias.

5. Statistical analysis

The data were analyzed using Review Manager 5.1. Endpoints were treated as dichotomous outcomes, and odds ratios (ORs) with 95% confidence intervals (CIs) were taken as a statistical indicator of the curative effect and safety of IABP in AMI. When the event of interest did not occur, the treatment effect of that study was treated as not estimable [9].

The Breslow–Day χ^2 test (p < 0.1) and the I^2 statistic were used to test heterogeneity of the 13 included studies. An I^2 of less than 25%, indicated low, $25\% < I^2 < 50\%$ moderate, p > 0.1; and $I^2 > 50$, a high degree of heterogeneity [4]. When $I^2 < 50\%$, a fixed-effects Mantel-Haenzel model was used to analyze the data, and when $I^2 > 50\%$, the DerSimonian and Laird random-effects model was found better than the former model. Publication bias was evaluated using funnel plots [5].

Results

1. Study sample selection characteristics

A total of 641 potentially eligible publications were retrieved during the searches, and 524 articles not associated with treatment of AMI with IABP were excluded by browsing the title or abstract (Figure 1). After further screening, an additional 104 articles were excluded, including 86 non-RCTs, 13 animal experiments, four case reports, and two articles involving other assist devices. The remaining 13 articles satisfied the selection criteria. The 13 studies enrolled 2237 AMI patients; 1112 were treated with IABP (the treatment group) and 1125 patients were not treated with IABP (the control group). The characteristics of the 13 articles are shown in Table 1. In four of the studies, participants in the IABP were AMI patients with CS; however, in the other eight studies, the patients did not have CS.

Acorrding to the PRISMA Statement [6], A flow diagram (Figure 1) and a 27-item checklist (Checklist S1) for transparent reporting of a systematic review were used to included in the papper.

2. Risk of bias within studies

The 13 selected RCTs provided complete dates of conduct and were free of selective reporting of results or risk of bias. However, three of the RCTs [8,17,18] did not clearly describe the methods of randomization or concealment of group allocation (Table 2).

3. Mortality within 2 months

Ten trials with a total of 973 AMI patients reported 2-month mortality. The I^2 statistic showed that study heterogeneity was significant (p = 0.03, $I^2 = 53\%$), and thus the random-effects model of DerSimonian and Laird was selected to analyze the data. There was no significant difference in 2-month mortality between the IABP group and the control group (three RCTs enrolled AMI patients with CS (OR = 0.67, 95% CI: 0.28–1.64; p = 0.39). Seven RCTs enrolled AMI without CS (OR = 1.60, 95% CI: 0.52–4.90; p = 0.41.). (Figure 2).

4. Mortality within 6-12 months

Seven trials, with a total sample size of 1500, reported 6–12month mortality. The study results did not show significant heterogeneity (P=0.21, $I^2=27\%$), and thus the fixed-effects Mantel–Haenzel model was used for data analysis. The 6-month mortality in the IABP group was not significantly lower than in the control group in the four RCTs that enrolled AMI patients with CS (OR = 0.90, 95% CI: 0.67–1.21; p = 0.49). But in the four that enrolled AMI patients without CS, the data showed opposite conclusion(OR = 0.53, 95% CI: 0.30–0.93; p = 0.03). (Figure 3). The funnel diagram was proximally symmetrical, which indicated no publication bias (Figure 4).

5. Bleeding events

A total of eight RCTs with a total sample size of 1485 reported bleeding events. The study results did not show significant heterogeneity (p = 0.85, $I^2 = 0\%$) and indicated that the risk of bleeding occurring in IABP patients in IABP was higher than in the control group (OR = 1.66, 95% CI: 1.25–2.20; p < 0.01) (Figure 5).

Discussion

This meta-analysis of 12 RCTs investigating treatment of AMI by IABP indicated that (1)IABP can not reduce within 2 months and 6–12 months mortality of AMI patients with cardiac shock (CS), as well as within 2 months mortality of AMI patients without CS, (2)but can reduce 6–12 months mortality of AMI patients without CS. (3)However, IABP increased the risk of bleeding.

Existing research shows that IABP increases blood supply to the coronary artery and the brain, reduces afterload, and eventually decreases cardiac oxygen consumption [1,2]. It can thus be considered as an adjuvant method for treatment of AMI. The difference in results for short- (1-2 months) and long-term (6-12 months)

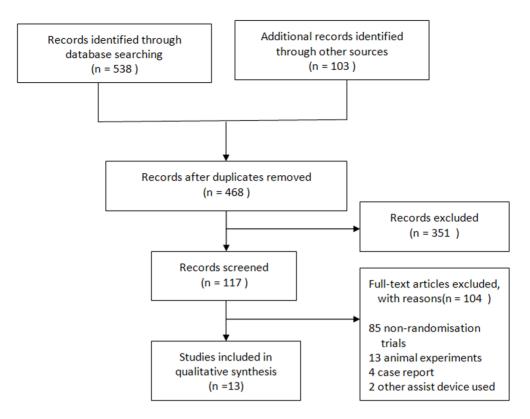


Figure 1. Meta-Analyses statement for trial selection. doi:10.1371/journal.pone.0108356.g001

months) follow-up indicates that treatment of AMI with IABP may be associated with some slow, compensatory mechanism of myocardial repair, but the specific mechanism is still not clear. A study by Chang [20], showed that in 2 months, the granulation scar tissue in the infarct area changed into connective tissue. In 2– 3 months, the infarct area changed into a complete, acellular fibrous scar. These changes in scar tissue are consistent with the effect of IABP on mortality in this meta-analysis and suggest that IABP treatment may be affected by some unknown factors associated with scar formation. More experiments should be conducted to determine the mechanism. Although IABP can reduce AMI patient mortality in the first 6–12 months, it also increases the risk of bleeding. This mechanism is also not clear, thus further studies are needed.

Since 1980s, IABP is widely used in clinic. AMI is commonly seen in internal medicine, and about $7\% \sim 10\%$ of AMI patients with CS has high mortality rate, through timely and effective treatment is performed. Coronary artery recanalization is the key to treat AMI, but in theory IABP can be used to better ensure sufficient blood supply and improve cardiac function of patients so as to save more myocardium and eventually further reduce the adverse consequence of AMI for patients. But, in the process of actual clinical research, the role of IABP is still controversial.

SHOCK registered study [21] and NRMI registered study [22] confirm that application of IABP obviously benefits patients. SHOCK research retrospectively analyzes 856 patients AMI combined with cardiac shock and shows that mortality rate in the hospital of IABP group is better than that of non IABP group (50% vs72%, P<0.0001). NRMI study evaluates American 23180 patients with AMI combined with cardiac shock registered, with total mortality of 70%; 31% of the patients are undergone IABP; among patients with venous thrombolysis, the application of IABP

is significantly correlated to case fatality rate (67% vs49%, P< 0.05); thrombolysis combined with IABP treatment can reduce the risk of death by 18% (OR0.82; 95%CI 0.72–0.93), but this study also puts forward that application of IABP is not obviously effective in emergency angioplasty(45% vs 47%).

Zeymer [23] retrospectively analyzed 653 cases of patients with acute STEMI and non acute STEMI combined with cardiac shock in 176 European medical centers from May, 2005 to April, 2008, showing only 25% of the patients with IABP in PCI surgery, and there was no significant difference in survival rate between IABP group and non IABP group(OR 1.47; 95% CI 0.97–2.21, P=0.07). Zeymer [24] carried out a retrospective analysis on 55008 cases of ACS patients (1913 cases combined with shock)with PCI treatment from January, 2006 to December, 2011, among of whom, 487 cases were undergone IABP treatment. The mortality in the hospital for patients with IABP and without IABP was 43.5% and 37.4%, respectively (P=0.0004), showing the application of IABP is obviously associated with higher fatality rate(OR 1.45,95% CI 1.15–1.84).

Valk [25] retrospectively analyzed 437 AMI patients with IABP from 1999 to 2004 (1990–2004 as the first stage, 1995–1999 as the second stage and 2000–2004 as the third stage), whose results showed that the amount of shock patients in three stages was not different; with the increase of ABP treatment, 30 d case fatality rate was reduced to 26% from 41%; about half of the patients still alive after ten years' follow-up.

In this meta-analysis, major adverse cardiac events (MACEs) were not analyzed because the details of relevant events have not been reported in most published studies. A retrospective study [26] including 1490 AMI patients showed that the occurrence of MACEs in AMI patients with CS was significantly reduced by treatment with IABP (14.5% in the IABP group vs. 35.1% in the

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Author(Year)	Patients(n)	IABP	Control	IABP	Control	Inclusion criteria	IABP	Control	IABP atter AMI(h)	IABP duration(n)	duration(d)
Flaherty 1985 [7]	20	6(0.06)	9(90.0)	52.0	52.0	AMI without CS	IABP+TT	F	5.0±2.6	34±25	60
Gu 2011 [8]	106	29(56.9)	36(65.5)	67.4	66.6	AMI without CS	IABP+PCI	PCI	5.3±1.9	52±17	30;180
Kono 1996 [9]	45	20(87.0)	16(72.7)	54.0	60.0	AMI without CS	IABP+PTCA	PTCA	2.5±0.5	48	21
Li 2007 [10]	39	12(60.0)	12(63.1)	67.4	64.9	AMI with CS	IABP+PCI	PCI	NR	72	360
Ohman 1994 [11]	182	73(75.6)	64(74)	56.0	55.0	AMI without CS	IABP+TT	Ħ	<24	12	6
Ohman 2005 [12]	57	23(77.0)	20(74.0)	68.0	67.0	AMI with CS	IABP+PCI	PCI	0.5(0.3–0.9), AR	34(24–68)	30;180
Patel 2011 [13]	337	132(82.0)	144(81.8)	56.1	57.7	AMI without CS	IABP+PCI	PCI	3.4(2.4–4.5)	22.1 (16.8–26.1)	180
Perera 2010 [14]	301	122(81.0)	117(78.0)	71.0	71.0	AMI without CS	IABP+PCI	PCI	<24 h, AR	4–24	30;180
Prondzinsky 2010 [15]	40	14(73.6)	17(80.9)	62.1	66.1	AMI with CS	IABP+PCI	PCI	13.91 ±3.06	96	4
Stone 1997 [16]	437	158(74.9)	170(75.2)	64.7	63.7	AMI without CS	IABP+PTCA	PTCA	12	47.9±28.0	30
Thiele 2013 [17]	595	299(66.9)	296(70.6)	Ŋ	NC	AMI with CS	IABP+PCI	PCI	UC	nc	12
Vijayalakshmi 2007 [18]	33	14(82.3)	14(87.5)	39.8	44.7	AMI without CS	IABP+PCI	PCI	7.1 ±5.5	48	30
Waksman 1993 [19]	45	14(58.3)	15(71.4)	66.8	67.8	AMI with CS	IABP+TT	F	3	228	30;180

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Table 2. Methodological quality assessment of the included articles.

Author	Random sequence generation (selection bias)	Allocation concealment(selection bias)	Blinding? (performance bias and detection bias)	Incomplete outcome data addressed?	Free of selective reporting? (reporting bias)	Free of other bias?
Flaherty 1985 [7]	Υ	Y	Y	Ν	Y	Y
Gu 2011 [8]	U	U	Υ	Υ	Υ	Y
Kono 1996 [9]	Y	Y	Ν	Υ	Υ	Y
Li 2007 [10]	Y	Y	Υ	Υ	Υ	Y
Ohman 1994 [11]	Y	Y	Υ	Υ	Υ	Y
Ohman 2005 [12]	Y	Y	Υ	Υ	Υ	Ν
Patel 2011 [13]	Y	Y	Υ	Υ	Y	Y
Perera 2010 [14]	Y	Y	Υ	Υ	Υ	Y
Prondzinsky 2010 [15]	Y	Y	Ν	Υ	Υ	Y
Stone 1997 [16]	Y	Y	Υ	Υ	Ν	Y
Thiele 2013 [17]	Y	Y	Ν	Y	Υ	Y
Vijayalakshmi 2007 [18]	U	U	Ν	Y	Y	Y
Waksman 1993 [19]	U	U	Ν	Y	Y	Y

N:No; U:Unclear; Y:Yes.

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control group, p = 0.009), and that IABP was also beneficial in AMI patients with decreased left ventricular function. Barron et al. [27] carry out a NRMI-2 study involved 23,180 AMI patients with CS, of whom, 7268 patients were performed with IABP treatment. The result shows that the mortality rate of patients with IABP treatment is significantly lower than that of patients with

thrombolytic therapy (67% vs49%). Unfortunately, most of the published studies were not RCTs. Besides, some studies with large sample sizes have yielded conflicting results [16,28].

Although similar meta-analyses have been published, their conclusions differ from those provided here. In a meta-analysis based on six RCTs (two of which included patients with

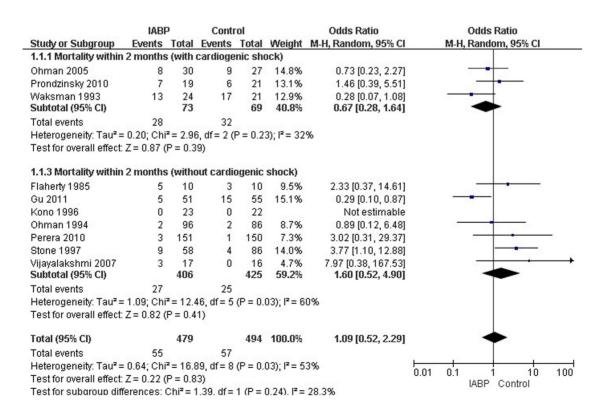


Figure 2. Forest plot of studies evaluating curative effect of IABP in mortality within 2 months. doi:10.1371/journal.pone.0108356.g002

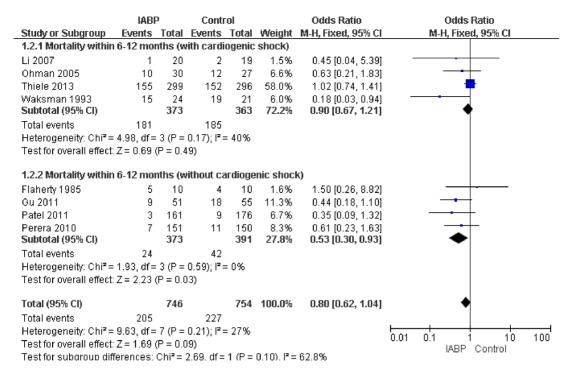


Figure 3. Forest plot of studies evaluating curative effect of IABP in mortality within 6–12 months. doi:10.1371/journal.pone.0108356.g003

percutaneous left ventricular assist devices in the control group), no convincing benefit was observed with IABP therapy in AMI patients with CS [29]. Another meta-analysis concluded that IABP did not reduce mortality in AMI patients without CS, but the data were not divided into subgroups based on follow-up duration [30]. Briefly, those analyses concluded that IABP might not benefit AMI patients. However, in this analysis, we came to the opposite conclusion when the data were stratified by different durations of follow-up. Without analyzing different follow-up time, a metaanalysis showed that IABP can not improve LVEF or reduce the occurrence of angina or infarction on AMI patients without CS

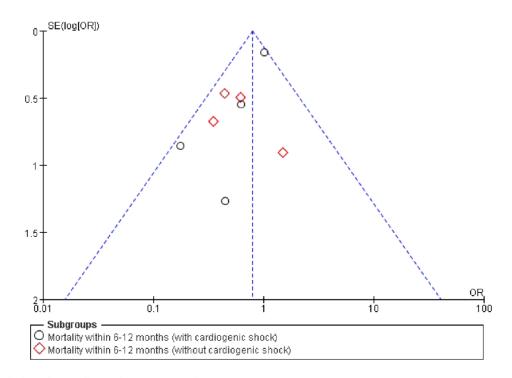


Figure 4. Funnel plot of mortality within 6–12 months. doi:10.1371/journal.pone.0108356.g004

	IABP Control Odds Ratio				Odds Ratio	Odds Ratio				
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl		M-H, Fixed, 9	5% CI	
Flaherty 1985	1	10	0	10	0.6%	3.32 [0.12, 91.60]		10	-	-
Gu 2011	6	51	2	55	2.3%	3.53 [0.68, 18.38]		1	3 20	
Kono 1996	5	23	6	22	6.4%	0.74 [0.19, 2.90]			2	
Ohman 1994	24	96	14	86	14.7%	1.71 [0.82, 3.58]		+-	-	
Ohman 2005	8	30	3	27	3.1%	2.91 [0.68, 12.37]		100		
Patel 2011	5	161	3	176	3.7%	1.85 [0.43, 7.86]			- 29	
Perera 2010	29	151	17	150	18.3%	1.86 [0.97, 3.55]			-	
Stone 1997	76	211	62	226	50.9%	1.49 [0.99, 2.23]		1		
Total (95% CI)		733		752	100.0%	1.66 [1.25, 2.20]		•		
Total events	154		107							
Heterogeneity: Chi ² =	3.31, df=	7 (P =	0.85); I ² =	= 0%					10	100
Test for overall effect:	Z= 3.49	(P = 0.0	005)				0.01	0.1 1 IABP Co	10 Introl	100

Figure 5. Forest plot of studies evaluating curative effect of IABP in bleeding events. doi:10.1371/journal.pone.0108356.g005

[31]. However, IABP reduced the mortality of AMI patients with CS, but it increased the incidence of stroke and bleeding.

The present study differs from similar, previously published meta-analyses in that (1) it includes the most recent RCTs; (2) follow-up time was divided into two periods so that the impact of follow-up time can be assessed; and (3) the AMI patients were divided into subgroups with and without CS, thus making it easier to analyze the mechanism of treatment of AMI with IABP.

The present analysis also has certain limitations. (1) The basic therapies for the patients included in the selected studies were different. (2) Both the start-time and duration of IABP differed in the selected studies. (3) The sample sizes of some of the RCTs were relatively small. (4) The quality of some studies was relatively low. (5) The follow-up time in most studies was not sufficiently long. (6) MACEs were not analyzed statistically. To solve these problems, more high-quality clinical studies with longer follow-up time and more detailed records are needed. To confirm the curative effect and safety of IABP in AMI patients, more rigorous studies with larger sample sizes, longer follow-up time and more detailed records should be conducted.

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Conclusions

IABP can not reduce within 2 months and 6–12 months mortality of AMI patients with CS, as well as within 2 months mortality of AMI patients without CS, but can reduce 6–12 months mortality of AMI patients without CS. In addition, IABP can increase the risk of bleeding.

Supporting Information

Checklist S1 PRISMA checklist. (DOC)

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Author Contributions

Conceived and designed the experiments: LY MZ QC. Performed the experiments: LY MZ. Analyzed the data: LY GL WD. Contributed reagents/materials/analysis tools: LY DK QC. Wrote the paper: LY MZ.

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