

# Intra-aortic Balloon Counterpulsation and Infarct Size in Patients with Acute Anterior Myocardial Infarction without Shock

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# Background

Le ballon de contrepulsion intraortique a une place dans la revascularisation en cas d'IDM avec état de choc.

# Objectif

Déterminer la place de IABO dans la révascularisation myocardique en cas d'IDM non compliqué d'état de choc.

# Design, Setting, and Patients

An open, multicenter, randomized controlled trial, the Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction (CRISPAMI) included 337 patients with acute anterior STEMI but without cardiogenic shock at 30 sites in 9 countries from June 2009 through February 2011.

# Intervention

Initiation of IABC before primary percutaneous coronary intervention (PCI) and continuation for at least 12 hours (IABC plus PCI) vs primary PCI alone.

# Main Outcome Measures

Infarct size expressed as a percentage of left ventricular (LV) mass and measured by cardiac magnetic resonance imaging performed 3 to 5 days after PCI. Secondary end points included all-cause death at 6 months and vascular complications and major bleeding at 30 days. Multiple imputations were performed for missing infarct size data.

**Table 1.** Baseline Characteristics

	Total (N = 337)	IABC Plus PCI (n = 161)	PCI Alone (n = 176)
Age, median (IQR), y	56.6 (48.4-65.6)	56.1 (48.3-64.3)	57.7 (48.6-66.4)
Male sex, No. (%)	276 (81.9)	132 (82.0)	144 (81.8)
Race, No. (%)			
American Indian/Alaska Native	1 (0.3)	0	1 (0.6)
Asian	152 (45.1)	75 (46.6)	77 (43.8)
Black	16 (4.7)	3 (1.9)	13 (7.4)
White	161 (47.8)	81 (50.3)	80 (45.5)
Other <sup>a</sup>	7 (2.1)	2 (1.2)	5 (2.8)
Height, median (IQR), cm	169.9 (163.1-177.0)	170.2 (165.1-175.8)	168.9 (162.8-178.1)
Weight, median (IQR), kg	74.3 (64.5-85.7)	74.4 (66.3-84.3)	74.4 (64.5-88.2)
Medical history, No. (%)			
Prior PCI	5 (1.5)	3 (1.9)	2 (1.1)
Hypertension (receiving drug therapy)	99 (29.4)	39 (24.2)	60 (34.1)
Stroke	1 (0.3)	0	1 (0.6)
Transient ischemic attack	1 (0.3)	0	1 (0.6)
Current nicotine use	107 (31.8)	53 (32.9)	54 (30.7)
Dyslipidemia (receiving drug therapy)	42 (12.5)	20 (12.4)	22 (12.5)
Prior atrial fibrillation	4 (1.2)	3 (1.9)	1 (0.6)
Renal insufficiency	6 (1.8)	2 (1.2)	4 (2.3)
Diabetes mellitus	63 (18.7)	27 (16.8)	36 (20.5)
Insulin-dependent	7 (11.1)	5 (18.5)	2 (5.6)
Non-insulin-dependent	56 (88.9)	22 (81.5)	34 (94.4)
Prior peripheral arterial disease	1 (0.3)	0	1 (0.6)
At presentation			
Blood pressure, median (IQR), mm Hg			
Systolic	131.0 (118.0-150.0)	130.0 (113.0-150.0)	135.0 (120.0-151.0)
Diastolic	80.0 (70.0-92.0)	80.0 (70.0-92.0)	80.0 (71.5-92.0)
Heart rate, median (IQR), beats/min	81.0 (71.0-94.0)	81.0 (71.0-93.0)	80.0 (70.0-94.0)
Degree of ST elevation in anterior leads, mm, No. (%)			
0-<2	0	0	0
2-<4	1 (0.3)	0	1 (0.6)
4-<6	135 (40.1)	61 (37.9)	74 (42.0)
≥6	201 (59.6)	100 (62.1)	101 (57.4)

Abbreviations: IABC, intra-aortic balloon counterpulsation; IQR, interquartile range; PCI, percutaneous coronary intervention.

<sup>a</sup>Patients unable to identify race using the available choices.

**Table 2. Procedural Characteristics**

	No. (%) of Patients <sup>a</sup>		
	Total (N = 337)	IABC Plus PCI (n = 161)	PCI Alone (n = 176)
PCI			
Performed	317 (94.3)	154 (96.3)	163 (92.6)
Not performed	19 (5.6)	6 (3.7)	13 (7.4)
Coronary artery bypass graft surgery instead	6 (1.8)	2 (1.3)	4 (2.3)
No infarct artery identified	7 (2.1)	1 (0.6)	6 (3.4)
Technical limitations	6 (1.8)	3 (1.9)	3 (1.7)
Infarct-related artery			
Left main	0	0	0
Left anterior descending	328 (97.6)	159 (99.4)	169 (96.0)
Left circumflex	0	0	0
Right coronary	1 (0.3)	0	1 (0.6)
No infarct-related artery identified	7 (2.1)	1 (0.6)	6 (3.4)
Infarct-related artery stenosis location			
Proximal	207 (62.9)	103 (64.8)	104 (61.2)
Mid	132 (40.1)	56 (35.2)	76 (44.7)
Distal	19 (5.8)	11 (6.9)	8 (4.7)
Infarct-related artery TIMI flow			
Preintervention grade			
0	215 (65.3)	105 (66.0)	110 (64.7)
1	34 (10.3)	18 (11.3)	16 (9.4)
2	50 (15.2)	26 (16.4)	24 (14.1)
3	30 (9.1)	10 (6.3)	20 (11.8)
Postintervention grade			
0	5 (1.5)	1 (0.6)	4 (2.4)
1	6 (1.8)	5 (3.2)	1 (0.6)
2	8 (2.5)	5 (3.2)	3 (1.8)
3	306 (94.2)	145 (92.9)	161 (95.3)
Interventions performed on non-infarct-related arteries	6 (1.9)	5 (3.2)	1 (0.6)
Left main	2 (<1)	1 (<1)	1 (<1)
Left circumflex	1 (<1)	1 (<1)	0
Right coronary	3 (<1)	3 (<1)	0
Time to treatment, median (IQR), min			
From symptom onset to first hospital contact	113.0 (65.0-175.0)	112.0 (78.0-180.0)	115.0 (62.0-175.0)
From first medical contact to first device (infarct-related artery) <sup>b</sup>	71.0 (47.0-105.0)	77.0 (53.0-114.0)	68.0 (40.0-100.0)
From symptom onset to first device (infarct-related artery)	196.0 (140.0-272.0)	202.5 (145.0-272.0)	193.0 (136.0-275.0)
First device used on infarct-related artery			
Aspiration thrombectomy	115 (36.2)	54 (34.8)	61 (37.4)
Balloon	152 (47.8)	78 (50.3)	74 (45.4)
Stent	51 (16.0)	23 (14.8)	28 (17.2)
Type of stent	309 (96.9)	147 (94.2)	162 (99.4)
Drug-eluting	149 (48.2)	69 (46.9)	80 (49.4)
Bare metal	165 (53.4)	79 (53.7)	86 (53.1)
Anticoagulant use			
Unfractionated heparin	261 (77.7)	127 (79.4)	134 (76.1)
Bivalirudin	57 (17.0)	24 (15.0)	33 (18.8)
Glycoprotein IIb/IIIa	154 (45.8)	79 (49.4)	75 (42.6)

Abbreviations: IABC, intra-aortic balloon counterpulsation; IQR, interquartile range; PCI, percutaneous coronary intervention; TIMI, Thrombolysis in Myocardial Infarction.

<sup>a</sup>Values expressed as number (percentage) unless otherwise indicated. The percentages are based on the total of nonmissing data. Data are missing for up to 34 patients.

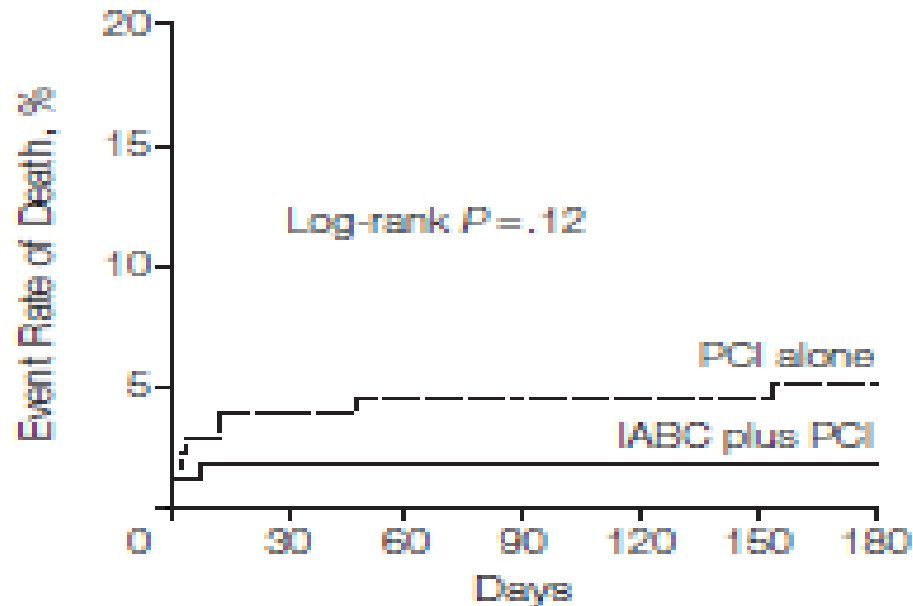
<sup>b</sup>The comparison between groups yielded a *P* value of .04.



**Table 3.** Cardiac Magnetic Resonance Imaging (MRI) Findings

	Total (N = 337)	IABC Plus PCI (n = 161)	PCI Alone (n = 176)	P Value
Time from symptom onset to MRI, median (IQR), d	4.0 (3.0-5.0)	4.0 (3.0-5.0)	4.0 (3.0-4.0)	.20
<b>Primary End Point</b>				
Infarct size, % of left ventricular mass				
Per-protocol analysis, No. (%)	275 (81.6)	133 (82.6)	142 (80.7)	
Mean (95% CI)	39.8 (37.4-42.1)	42.1 (38.7-45.6)	37.5 (34.3-40.8)	.06
Median (IQR)	38.8 (26.0-52.2)	42.8 (27.2-54.7)	36.2 (25.9-49.4)	
Multiple imputation analysis				
Mean (95% CI)	39.7 (37.3-42.1)	42.1 (38.6-45.6)	37.6 (34.3-40.9)	.07
Median (IQR)	39.0 (26.0-52.3)	42.5 (27.1-55.9)	36.4 (24.9-49.9)	
Proximal left anterior descending and TIMI flow score of 0 or 1				
Per-protocol analysis, No. (%)	192 (57.0)	93 (57.8)	99 (56.3)	
Mean (95% CI)	44.4 (41.7-47.1)	46.7 (42.8-50.6)	42.3 (38.6-45.9)	.11
Median (IQR)	42.1 (30.3-54.7)	45.1 (32.7-60.8)	38.6 (29.6-51.6)	
Multiple imputation analysis				
Mean (95% CI)	44.4 (41.7-47.1)	46.8 (42.9-50.8)	42.1 (38.4-45.7)	.08
Median (IQR)	42.5 (30.3-55.9)	45.3 (32.3-61.6)	39.2 (29.5-51.9)	
<b>Secondary End Point</b>				
MRI findings for ITT population				
Microvascular obstruction, No. (%)	274 (81.3)	131 (81.4)	143 (81.3)	.34
Mean (95% CI), %	6.2 (5.2-7.3)	6.8 (5.2-8.3)	5.7 (4.3-7.2)	
Median (IQR), %	2.6 (0.0-9.1)	2.8 (0.0-9.7)	2.0 (0.0-7.8)	
Left ventricular ejection fraction, No. (%)	284 (84.3)	136 (84.5)	148 (84.1)	.17
Mean (95% CI), %	47.2 (45.7-48.7)	46.1 (43.9-48.3)	48.2 (46.2-50.3)	
Median (IQR), %	46.9 (38.6-56.5)	46.2 (37.4-56.1)	47.6 (39.6-56.8)	
Left ventricular end-systolic volume, No. (%)	284 (84.3)	136 (84.5)	148 (84.1)	.10
Mean (95% CI), mL	73.5 (69.6-77.3)	76.9 (70.6-83.2)	70.3 (65.8-74.9)	
Median (IQR), mL	68.8 (51.0-86.0)	69.5 (51.7-86.5)	67.9 (49.2-86.0)	
Left ventricular end-diastolic volume, No. (%)	284 (84.3)	136 (84.5)	148 (84.1)	.32
Mean (95% CI), mL	137.5 (132.2-142.8)	140.3 (132.5-148.1)	134.9 (127.8-142.1)	
Median (IQR), mL	131.6 (107.4-166.6)	135.4 (112.0-166.8)	130.5 (103.9-166.5)	
Salvage index, No. (%)	263 (78.0)	126 (78.3)	137 (77.8)	.13
Mean (95% CI)	0.35 (0.32-0.38)	0.32 (0.27-0.37)	0.37 (0.33-0.41)	
Median (IQR)	0.30 (0.10-0.50)	0.30 (0.10-0.50)	0.30 (0.20-0.50)	

**Figure 2.** Event Rate of Death From 0 to 180 Days



No. at risk		0	30	60	90	120	150	180
PCI alone		174	167	165	165	165	165	164
IABC plus PCI		157	154	153	153	153	153	153

IABC indicates Intra-aortic balloon counterpulsation; PCI, percutaneous coronary intervention.

# CONCLUSION

Etude comparative entre deux groupes de malades atteints d'un IDM sans état de choc. L'une traité par angioplastie après IABO; l'autre avec angioplastie seul. Le résultat n'a pas montré une différence entre le deux groupes d'où la conclusion que le ballon de contrepulsion intraortique n' a pas de place dans la révascularisation myocardique dans l'IDM non compliqué en cas d'état de choc.