



2018/12/4 星期二

IABP-SHOCK II trial - CS complicating AMI, a Hot Potato

心源性休克是指由于收缩压 (systolic blood pressure, SBP) 持续 $<90\text{mmHg}$ ，心脏泵血功能衰竭，心排出量不足，组织缺血缺氧导致进一步微循环障碍而引起的临床综合征。6-10%的STEMI患者可能发生心源性休克，其中住院期间死亡率高达50%，至今仍是临床的一块烫手山芋。ESC STEMI 2017版指南建议临床应该考虑将主动脉内球囊反搏 (intra-aortic balloon pump, IABP) 作为机械性并发症(mechanical complication)引发的心源性休克的非药物治疗方法(推荐级别为IIa，证据水平C)¹。

1. “2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: The Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC)” – 欢迎各位专家访问CBS – Scientific Library 阅览及下载第八章有关STEMI并发症的指南推荐内容 (8.2.2.2 Management of cardiogenic shock) 或详见图一▶

<http://www.cbsmd.org/CBS2017CMS/scientificresearch.php?cid=105&id=37&oldpage=1&ordertype=posttime&page=1>



Recommendations for the management of cardiogenic shock in ST-elevation myocardial infarction

Recommendations	Class ^a	Level ^b
Immediate PCI is indicated for patients with cardiogenic shock if coronary anatomy is suitable. If coronary anatomy is not suitable for PCI, or PCI has failed, emergency CABG is recommended. ²⁴⁸	I	B
Invasive blood pressure monitoring with an arterial line is recommended.	I	C
Immediate Doppler echocardiography is indicated to assess ventricular and valvular functions, loading conditions, and to detect mechanical complications.	I	C
It is indicated that mechanical complications are treated as early as possible after discussion by the Heart Team.	I	C
Oxygen/mechanical respiratory support is indicated according to blood gases.	I	C
Fibrinolysis should be considered in patients presenting with cardiogenic shock if a primary PCI strategy is not available within 120 min from STEMI diagnosis and mechanical complications have been ruled out.	IIa	C
Complete revascularization during the index procedure should be considered in patients presenting with cardiogenic shock.	IIa	C
Intra-aortic balloon pumping should be considered in patients with haemodynamic instability cardiogenic shock due to mechanical complications.	IIa	C
Haemodynamic assessment with pulmonary artery catheter may be considered for confirming diagnosis or guiding therapy. ⁴³³	IIb	B

图一

ESC STEMI 2017 版指南与此有关内容的制定参考了 IABP-SHOCK II 的研究结果，即 IABP 并不能改善心梗并发心源性休克患者的预后，IABP-SHOCK II 试验的中性结果使 IABP 在国际指南中的推荐级别下降。现在关于 IABP 对急性心肌梗死并发心源性休克患者的长期临床结局影响的随机试验数据尚不充分。Holger Thiele 等研究者发表于 Circulation 的 IABP-SHOCK II 试验是一项多中心、随机、开放标签试验。纳入 2009 年~2012 年 600 例急性心肌梗死并发心源性休克的接受早期血运重建的患者，随机分为 IABP 组和对照组。2013 年 11 月发布的随访 1 年结果² 和 2018 年 11 月发布的随访 6 年结果³ 均显示 IABP 组与对照组之间主要终点全因死亡，次要终点复发性心肌梗死、卒中、再次血运重建或再入院治疗等方面无统计学差异；换言之，急性心肌

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梗死并发心源性休克患者的死亡率仍居高不下，IABP 对该人群无论短期还是长期全因死亡率无改善作用。

Thiele et al

Long-Term Follow-Up of IABP-SHOCK II

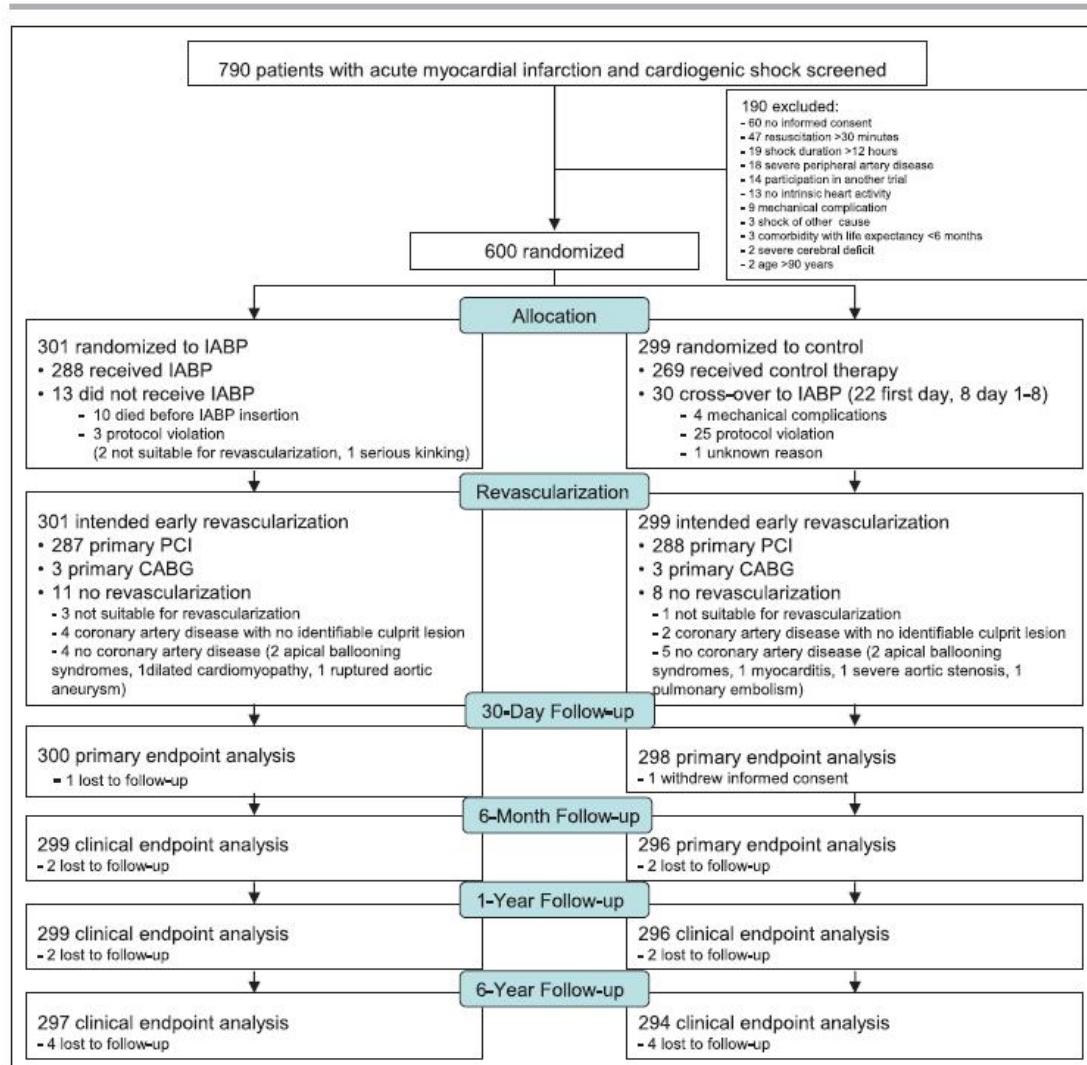


Figure 1. Trial flow.

Screening, randomization, revascularization, management strategy, and follow-up at 30 days, 6 months, 12 months, and 6 years. CABG indicates coronary artery bypass grafting; IABP, intraaortic balloon pump; and PCI, percutaneous coronary intervention.

2. “ Intra-aortic balloon counterpulsation in acute myocardial infarction complicated by cardiogenic shock (IABP-SHOCK II): final 12 month results of a randomised, open-label trial” ►

<http://www.cbsmd.org/CBS2017CMS/scientificresearch.php?cid=127&id=1551&oldpage=1&ordertype=hits&page=1>

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3. “Intraaortic Balloon Pump in Cardiogenic Shock Complicating Acute Myocardial Infarction: Long-Term 6-Year Outcome of the Randomized IABP-SHOCK II Trial” ►
<http://www.cbsmd.org/CBS2017CMS/scientificresearch.php?cid=127&id=1549&oldpage=1&ordertype=hits&page=1>

Table 1. Clinical Outcomes at 6 Years

Variable	Intraaortic Balloon Pump (n=297)	Control (n=294)	Relative Risk (95% CI)	P Value
All-cause mortality	197/297 (66.3)	197/294 (67.0)	0.99 (0.88–1.11)	0.98
Events in 6-year survivors				
Reinfarction	9/100 (9.0)	7/97 (7.2)	1.25 (0.48–3.22)	0.65
Stroke	1/100 (1.0)	6/97 (6.2)	0.16 (0.02–1.32)	0.06
Recurrent revascularization	26/100 (26.0)	31/97 (32.0)	0.81 (0.52–1.26)	0.36
Repeat percutaneous coronary intervention	18/100 (18.0)	26/97 (26.8)	0.67 (0.39–1.14)	0.14
Additional coronary artery bypass grafting	8/100 (8.0)	7/97 (7.2)	1.11 (0.42–2.94)	0.84
Implantable cardioverter defibrillator implantation	13/100 (13.0)	15/97 (15.5)	0.84 (0.42–1.67)	0.62

Values indicate n/total (%).

IABP-SHOCK II 研究 6 年随访主要终点及次要终点结果

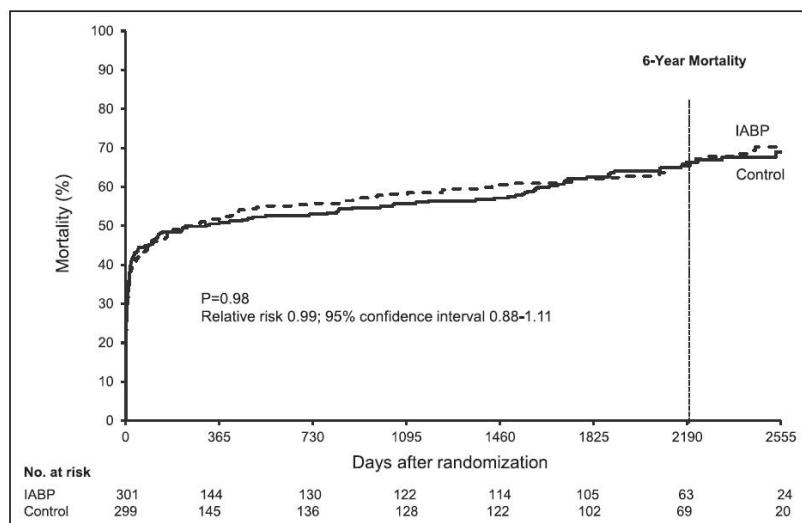


Figure 2. Time-to-event curves through 6 years.

Time-to-event curves through 6 years for all-cause mortality. P value is based on the log-rank test. Event rates represent Kaplan-Meier estimates. IABP indicates intraaortic balloon pump.

IABP-SHOCK II 研究 6 年主要研究终点事件发生率曲线



IABP-SHOCK II 研究数据除用于以上研究目的之外的其他用途：

2016 年 12 月 “Culprit lesion location and outcome in patients with cardiogenic shock complicating myocardial infarction: a substudy of the IABP-SHOCK II-trial” 子研究揭示罪犯病变多见于前降支（44%），其他部位罪犯血管分布分别为 RCA (27 %), LCX (19 %) 或 LM (10 %)。尽管近端病变较中段或远端病变更常见，但远端罪犯病变波及 AMI 合并 CS 患者的 1 年后死亡率更高►

<http://www.cbsmd.org/CBS2017CMS/scientificresearch.php?cid=127&id=1564&oldpage=1&ordertype=hits&page=1>

2018 年 6 月发表的回顾性分析 “Prognostic impact of baseline glucose levels in acute myocardial infarction complicated by cardiogenic shock-a substudy of the IABP-SHOCK II-trial” 结论显示，AMI 合并 CS 患者的入院血糖异常升高是 30 天和 1 年的死亡率独立预测因子，且与糖尿病史无关►

<http://www.cbsmd.org/CBS2017CMS/scientificresearch.php?cid=127&id=1553&oldpage=1&ordertype=hits&page=1>

2018 年 3 月公布的 “Prognostic impact of atrial fibrillation in cardiogenic shock complicating acute myocardial infarction: a substudy



of the IABP-SHOCK II trial”分析结果显示揭示，房颤 (atrial fibrillation, AF) 占 IABP-SHOCK II 研究人群的接近三分之一，但房颤并不与 AMI 合并 CS 患者的 30 天和 1 年的临床结局相关▶

<http://www.cbsmd.org/CBS2017CMS/scientificresearch.php?cid=127&id=155&oldpage=1&ordertype=hits&page=1>

2018 年 6 月发表的“Prognostic impact of non-culprit chronic total occlusions in infarct-related cardiogenic shock: results of the randomised IABP-SHOCK II trial”亚分析进一步发现非梗死相关动脉 (non-infarct-related artery, non-IRA) 的 CTO 病变与 AMI 合并 CS 患者心室率失常相关，可独立预测该人群的 1 年死亡率▶

<http://www.cbsmd.org/CBS2017CMS/scientificresearch.php?cid=127&id=155&oldpage=1&ordertype=hits&page=1>

其他可辅助临床决策的 IABP-SHOCK II 研究组成果；“Risk Stratification for Patients in Cardiogenic Shock After Acute Myocardial Infarction”▶

<http://www.cbsmd.org/CBS2017CMS/scientificresearch.php?cid=127&id=156&oldpage=1&ordertype=hits&page=1>