STEMI合并休克 IABP应用时机及撤机标准

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- 应用时机：何时置入？
- 撤机标准：持续时间？

IABP in AMI complicated by cardiogenic shock

	2012年之前	2012年之后
ESC	Class I /C	→ IIb /B, III /A
ACC/AHA	Class I /B	→ IIa /B

European Heart Journal
doi:10.1093/eurheartj/ehv320

ESC GUIDELINES

2015 ESC guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation

Routine use of IABP in patients with cardiogenic shock is not recommended.	III	B

2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation

Routine intra-aortic balloon pumping is not indicated.[177,437]	III	B

shock.[176] In addition, a recent randomized trial showed that IABP did not improve outcomes in MI with cardiogenic shock.[177] Haemodynamic support in patients with cardiogenic shock is discussed in

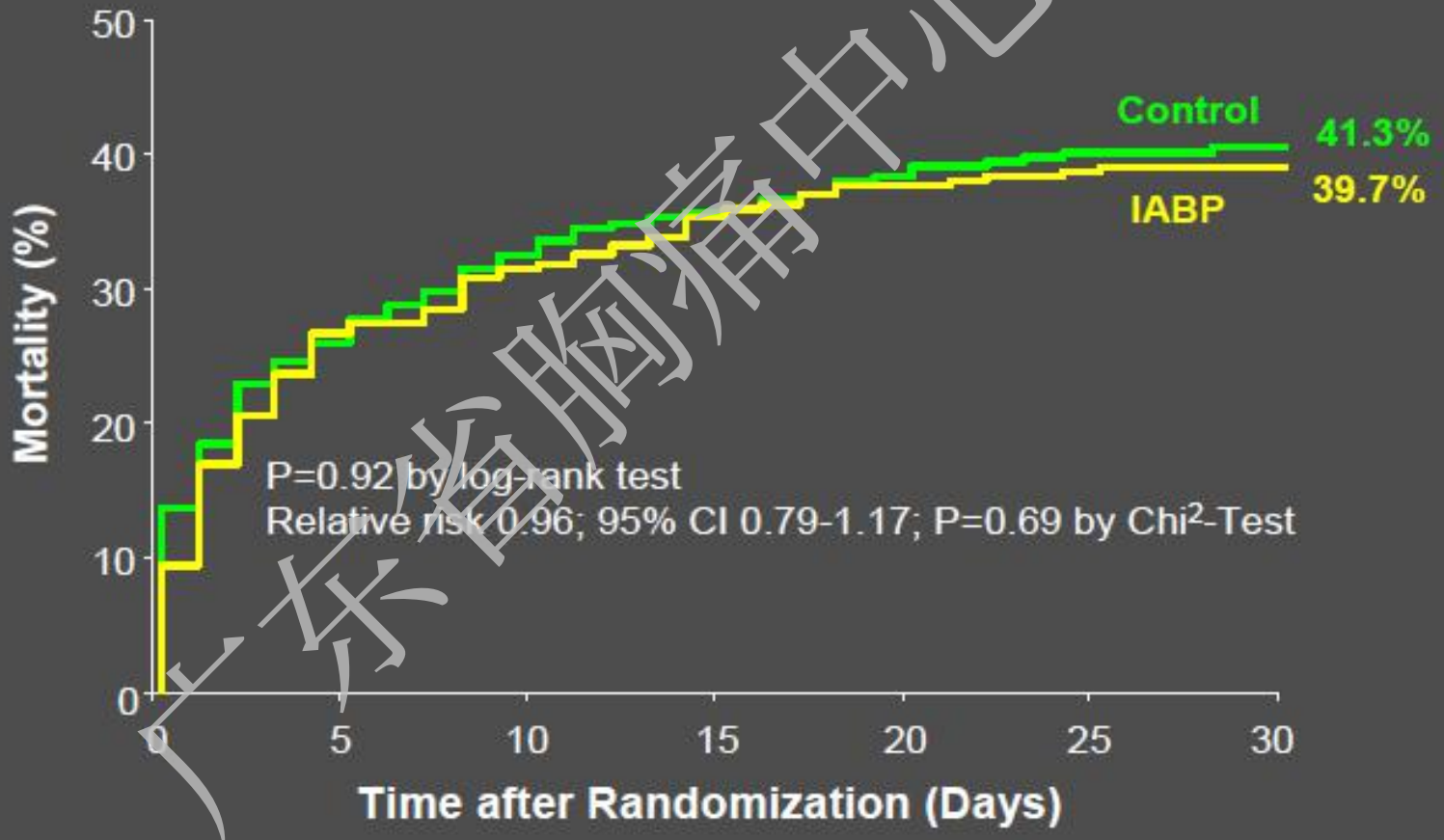
IABP SHOCK II研究

- 2009年6月-2012年3月，600例心源性休克患者，接受早期再血管化（PCI或CABG）。随机分为：IABP 组 (n=301)；对照组 (n=299)
- 主要终点：30天死亡率，12个月死亡率
- 次要终点：血液动力学稳定时间，住监护室时间，血乳酸值，儿茶酚胺类药物剂量及使用时间，肾功能均无显著差异

IABP-SHOCK II（主要终点：30天死亡率）

Results

Primary Study Endpoint (30-Day Mortality)

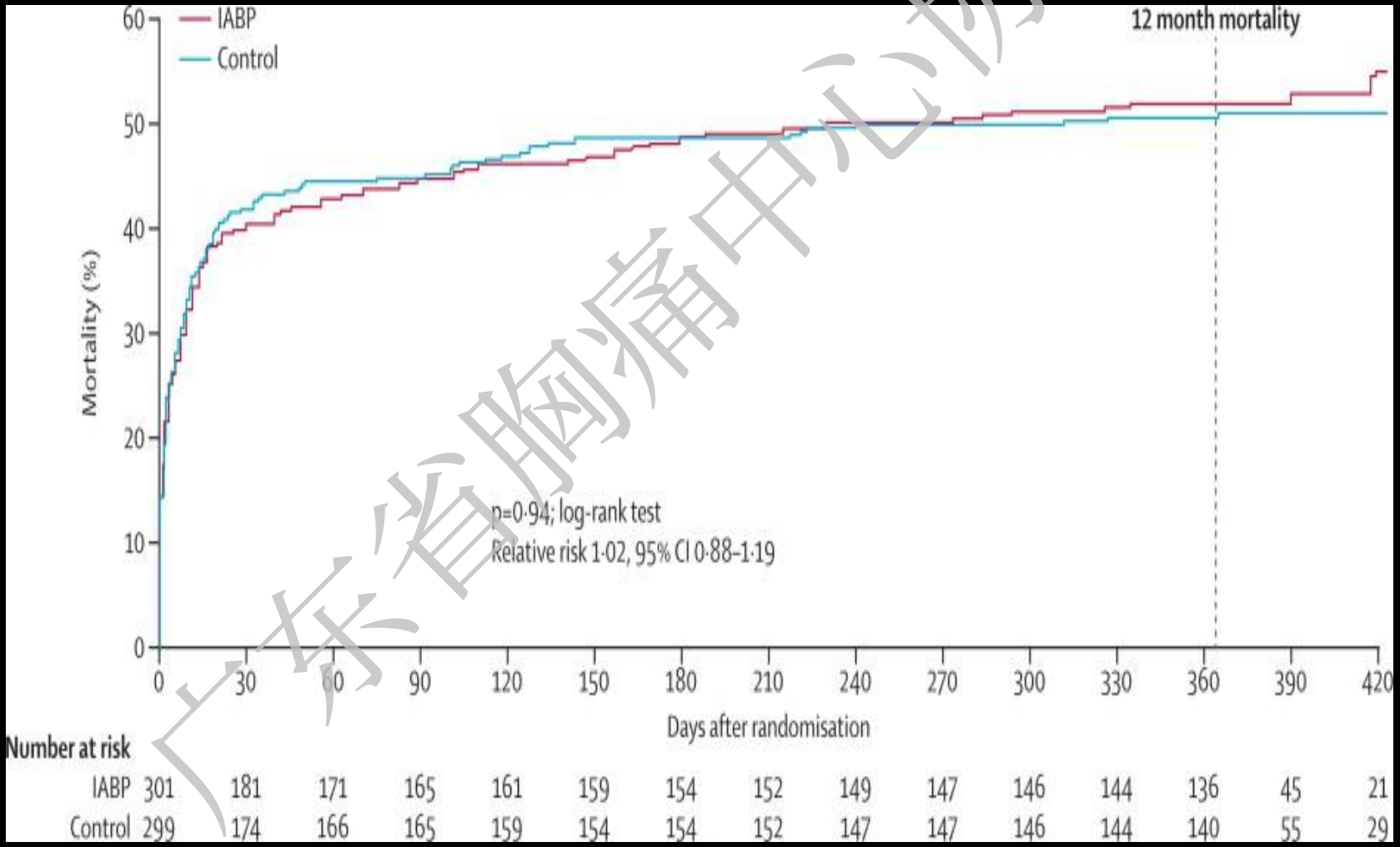


THE LANCET
Volume 382, Issue 9905, 16–22 November 2013, Pages 1638–1645

Articles

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

12个月随访结果



IABP-Shock II 研究结论

- AMI合并心源性休克时使用IABP是安全的，无严重并发症
- 对AMI合并心源性休克患者早期血管重建同时使用IABP不能减少30天死亡率
- 对AMI合并心源性休克患者早期血管重建同时使用IABP不能减少12个月死亡率

仔细分析IABP-Shock II 研究：

阴性结果是否与IABP应用时机和撤机时机有关？

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 4, 2012 VOL. 367 NO. 14

Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

Holger Thiele, M.D., Uwe Zeymer, M.D., Franz-Josef Neumann, M.D., Miroslaw Ferenc, M.D., Hans-Georg Olbrich, M.D., Jörg Hausleiter, M.D., Gert Richardt, M.D., Marcus Hennersdorf, M.D., Klaus Empen, M.D., Georg Fuernau, M.D., Steffen Desch, M.D., Ingo Eitel, M.D., Rainer Hambrecht, M.D., Jörg Fuhrmann, M.D., Michael Böhm, M.D., Henning Ebelt, M.D., Steffen Schneider, Ph.D., Gerhard Schuler, M.D., and Karl Werdan, M.D., for the IABP-SHOCK II Trial Investigators*

ABSTRACT

BACKGROUND

In current international guidelines, intraaortic balloon counterpulsation is considered to be a class I treatment for cardiogenic shock complicating acute myocardial infarction. However, evidence is based mainly on registry data, and there is a paucity of randomized clinical trials.

METHODS

In this randomized, prospective, open-label, multicenter trial, we randomly assigned 600 patients with cardiogenic shock complicating acute myocardial infarction to intraaortic balloon counterpulsation (IABP group, 301 patients) or no intraaortic balloon counterpulsation (control group, 299 patients). All patients were expected to undergo early revascularization (by means of percutaneous coronary intervention or bypass surgery) and to receive the best available medical therapy. The primary efficacy end point was 30-day all-cause mortality. Safety assessments included major bleeding, peripheral ischemic complications, sepsis, and stroke.

RESULTS

A total of 300 patients in the IABP group and 298 in the control group were included in the analysis of the primary end point. At 30 days, 119 patients in the IABP group (39.7%) and 123 patients in the control group (41.3%) had died (relative risk with IABP, 0.96; 95% confidence interval, 0.79 to 1.17; P=0.69). There were no significant differences in secondary end points or in process-of-care measures, including the time to hemodynamic stabilization, the length of stay in the intensive care unit, serum lactate levels, the dose and duration of catecholamine therapy, and renal function. The IABP group and the control group did not differ significantly with respect to the rates of major bleeding (3.3% and 4.4%, respectively; P=0.51), peripheral ischemic complications (4.3% and 3.4%, P=0.53), sepsis (15.7% and 20.9%, P=0.15), and stroke (0.7% and 1.7%, P=0.28).

CONCLUSIONS

The use of intraaortic balloon counterpulsation did not significantly reduce 30-day mortality in patients with cardiogenic shock complicating acute myocardial infarction for whom an early revascularization strategy was planned. (Funded by the German Research Foundation and others; IABP-SHOCK II ClinicalTrials.gov number, NCT00491036.)

From the University of Leipzig-Heart Center, Leipzig (H.T., G.F., S.D., G.S.), Klinikum Ludwigshafen and Institut für Herzinfarktforschung, Ludwigshafen (S.S.), Heart Center Bad Krozingen, Bad Krozingen (F.-J.N., M.H.), Asklepios Clinic Langen-Seligenstadt, Langen (H.-G.O.), German Heart Center Munich, Munich (J.H.), Heart Center Siegburg, Siegburg (G.R.), Klinikum Lüdenscheid, Lüdenscheid (K.E.), Klinikum Lüneburg, Lüneburg (R.H.), Zentralklinik Bad Berka, Bad Berka (J.F.), University Clinic of Saarland, Homburg/Saar (M.B.), and Martin-Luther University Halle-Wittenberg, Halle (H.E., K.W.) — all in Germany. Address reprint requests to Dr. Thiele at the University of Leipzig–Heart Center, Department of Internal Medicine–Cardiology, Strümpellstr. 39, 04289 Leipzig, Germany, or at thiele@medizin.uni-leipzig.de.

Drs. Schuler and Werdan contributed equally to this article.

*Investigators in the Intraaortic Balloon Pump in Cardiogenic Shock II (IABP-SHOCK II) trial are listed in the Supplementary Appendix, available at NEJM.org.

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Articles

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

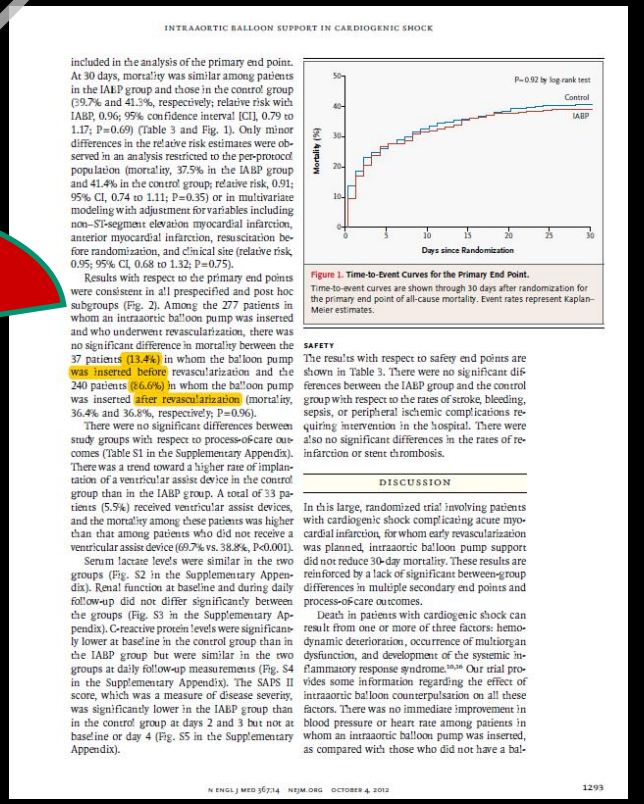
Prof Holger Thiele, MD[a], Prof Uwe Zeymer, MD[b], Prof Franz-Josef Neumann, MD[c], Miroslaw Ferenc, MD[c], Prof Hans-Georg Olbrich, MD[d], Prof Jörg Hausleiter, MD[e], Antoinette de Waha, MD[f], Prof Gert Richardt, MD[g], Prof Marcus Hennersdorf, MD[h], Klaus Empen, MD[i], Georg Fuernau, MD[a], Steffen Desch, MD[a], Ingo Eitel, MD[a], Prof Rainer Hambrecht, MD[j], Prof Bernward Lauer, MD[k], Prof Michael Böhm, MD[l], Henning Ebelt, MD[m], Steffen Schneider, PhD[b], Prof Karl Werdan, MD[m,*], Prof Gerhard Schuler, MD[a,*], on behalf of the Intraaortic Balloon Pump in cardiogenic shock II (IABP-SHOCK II) trial investigators[†]

应用时机：何时置入？

IABP SHOCK 2研究：

仅13.4%的患者为血运重建术前置入

37 patients (13.4%) in whom the balloon pump was inserted before revascularization and the 240 patients (86.6%) in whom the balloon pump was inserted after revascularization (mortality,



INTRAAORTIC BALLOON SUPPORT IN CARDIOGENIC SHOCK

included in the analysis of the primary end point. At 30 days, mortality was similar among patients in the IABP group and those in the control group (39.7% and 41.3%, respectively; relative risk with IABP, 0.96; 95% confidence interval [CI], 0.79 to 1.17; P=0.69) (Table 3 and Fig. 1). Only minor differences in the relative risk estimates were observed in an analysis restricted to the per-protocol population (mortality, 37.5% in the IABP group and 41.4% in the control group; relative risk, 0.91; 95% CI, 0.74 to 1.11; P=0.35) or in multivariate modeling with adjustment for variables including non–ST-segment elevation myocardial infarction, anterior myocardial infarction, resuscitation before randomization, and clinical site (relative risk, 0.95; 95% CI, 0.68 to 1.32; P=0.75).

Results with respect to the primary end points were consistent in all prespecified and post hoc subgroups (Fig. 2). Among the 277 patients in whom an intraaortic balloon pump was inserted and who underwent revascularization, there was no significant difference in mortality between the 37 patients (13.4%) in whom the balloon pump was inserted before revascularization and the 240 patients (86.6%) in whom the balloon pump was inserted after revascularization (mortality, 36.4% and 36.8%, respectively; P=0.96).

There were no significant differences between study groups with respect to process-of-care outcomes (Table S1 in the Supplementary Appendix). There was a trend toward a higher rate of implantation of a ventricular assist device in the control group than in the IABP group. A total of 33 patients (5.5%) received ventricular assist devices, and the mortality among these patients was higher than that among patients who did not receive a ventricular assist device (69.7% vs. 38.8%, P<0.001).

Serum lactate levels were similar in the two groups (Fig. S2 in the Supplementary Appendix). Renal function at baseline and during daily follow-up did not differ significantly between the groups (Fig. S3 in the Supplementary Appendix). C-reactive protein levels were significantly lower at baseline in the control group than in the IABP group but were similar in the two groups at daily follow-up measurements (Fig. S4 in the Supplementary Appendix). The SAPS II score, which was a measure of disease severity, was significantly lower in the IABP group than in the control group at days 2 and 3 but not at baseline or day 4 (Fig. S5 in the Supplementary Appendix).

Figure 1. Time-to-Event Curves for the Primary End Point.
Time-to-event curves are shown through 30 days after randomization for the primary end point of all-cause mortality. Event rates represent Kaplan–Meier estimates.

SAFETY

The results with respect to safety end points are shown in Table 3. There were no significant differences between the IABP group and the control group with respect to the rates of stroke, bleeding, sepsis, or peripheral ischemic complications requiring intervention in the hospital. There were also no significant differences in the rates of reinfarction or stent thrombosis.

DISCUSSION

In this large, randomized trial involving patients with cardiogenic shock complicating acute myocardial infarction, for whom early revascularization was planned, intraaortic balloon pump support did not reduce 30-day mortality. These results are reinforced by a lack of significant between-group differences in multiple secondary end points and process-of-care outcomes.

Death in patients with cardiogenic shock can result from one or more of three factors: hemodynamic deterioration, occurrence of multiorgan dysfunction, and development of the systemic inflammatory response syndrome.[16,26] Our trial provides some information regarding the effect of intraaortic balloon counterpulsation on all these factors. There was no immediate improvement in blood pressure or heart rate among patients in whom an intraaortic balloon pump was inserted, as compared with those who did not have a bal-

N Engl J Med. 2012; 367(14):1287-96.

Efficacy of Intra-aortic Balloon Pump before versus after Primary Percutaneous Coronary Intervention in Patients with Cardiogenic Shock from ST-elevation Myocardial Infarction

Lin Yuan[1,2], Shao-Ping Nie[1,2]

However, B-type natriuretic peptide levels were similar between two groups. However, IABP therapy before PCI was associated with better myocardial perfusion, characterized by lower rate of MBG 0/1 and none STR (STR < 30%) ($P < 0.05$).

In conclusion, our study showed that early IABP insertion before primary PCI is associated with a delay of DBT. However, myocardial perfusion is markedly improved with IABP therapy before PCI. Overall, IABP support before PCI does not confer a 12-month clinical benefit when used for STEMI with CS. More studies are needed to confirm our findings.

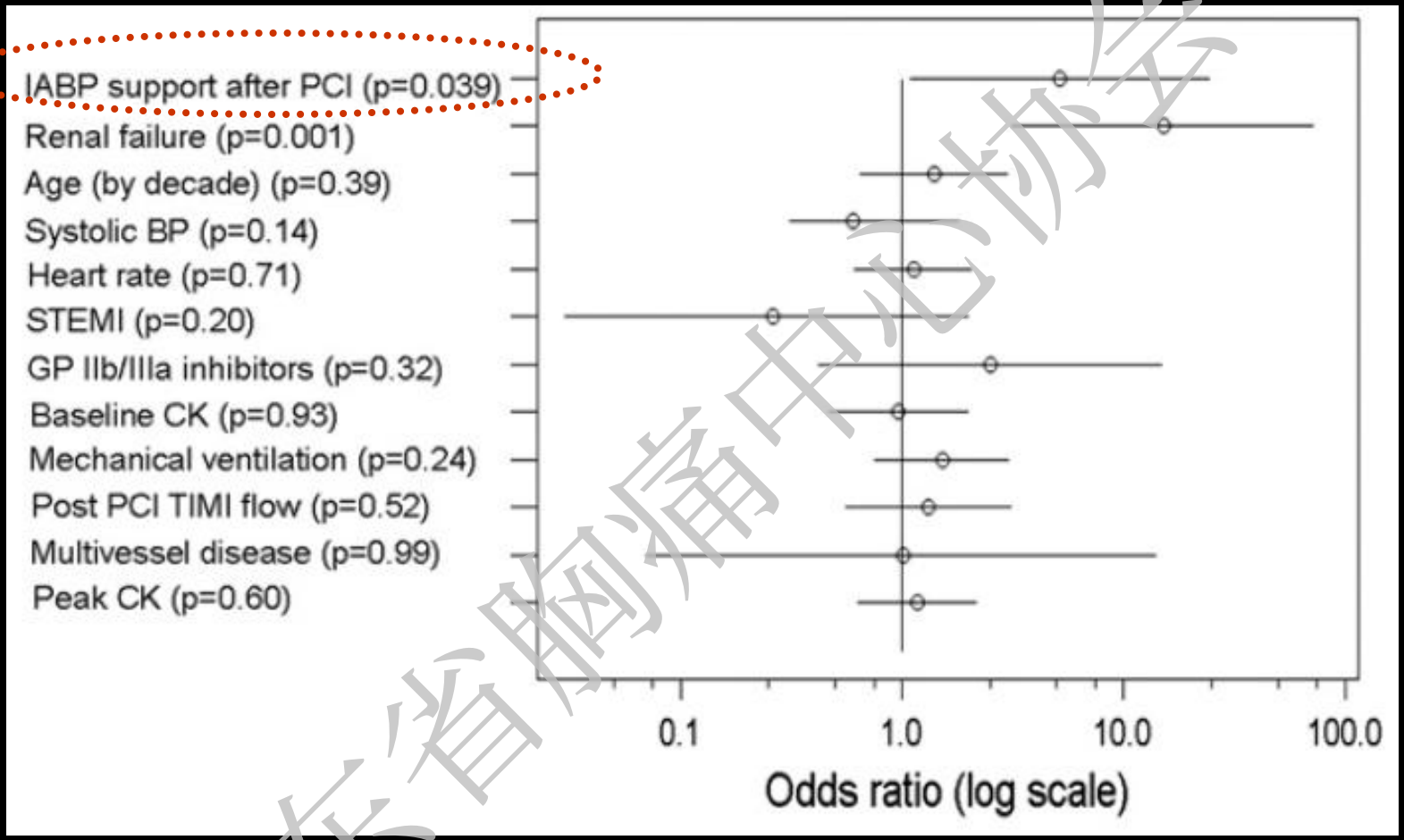
Chinese medical journal 2016, 129(12):1400-1405.

Comparison of Hospital Mortality With Intra-Aortic Balloon Counterpulsation Insertion Before Versus After Primary Percutaneous Coronary Intervention for Cardiogenic Shock Complicating Acute Myocardial Infarction

Mohamed Abdel-Wahab, MD*,†, Mohammed Saad, MD†, Joerg Kynast, MD, Volker Geist, MD, Mohammad A. Sherif, MD, Gert Richardt, MD, and Ralph Toelg, MD

	PCI术前置入	PCI术后置入	*P*
In-hospital death	5 (19%)	13 (59%)	0.007
Emergency coronary bypass	0	2 (9%)	0.20
Cerebrovascular events	2 (8%)	2 (9%)	1.00
Major adverse cardiac and cerebrovascular events	6 (23%)	17 (77%)	0.0004
Renal failure	6 (23%)	11 (50%)	0.072
Bleeding	6 (23%)	3 (14%)	0.48

Am J Cardiol. 2010; 105(7):967-71



Results of multivariate analysis for predictors of in-hospital mortality

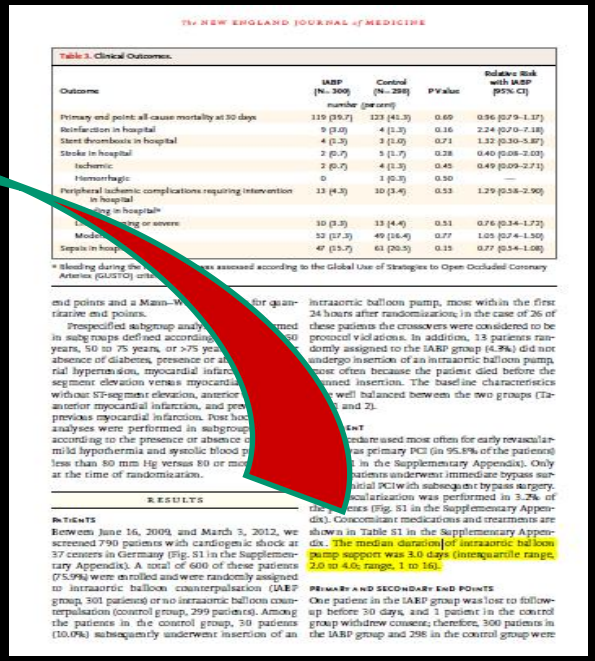
Am J Cardiol. 2010; 105(7):967-71

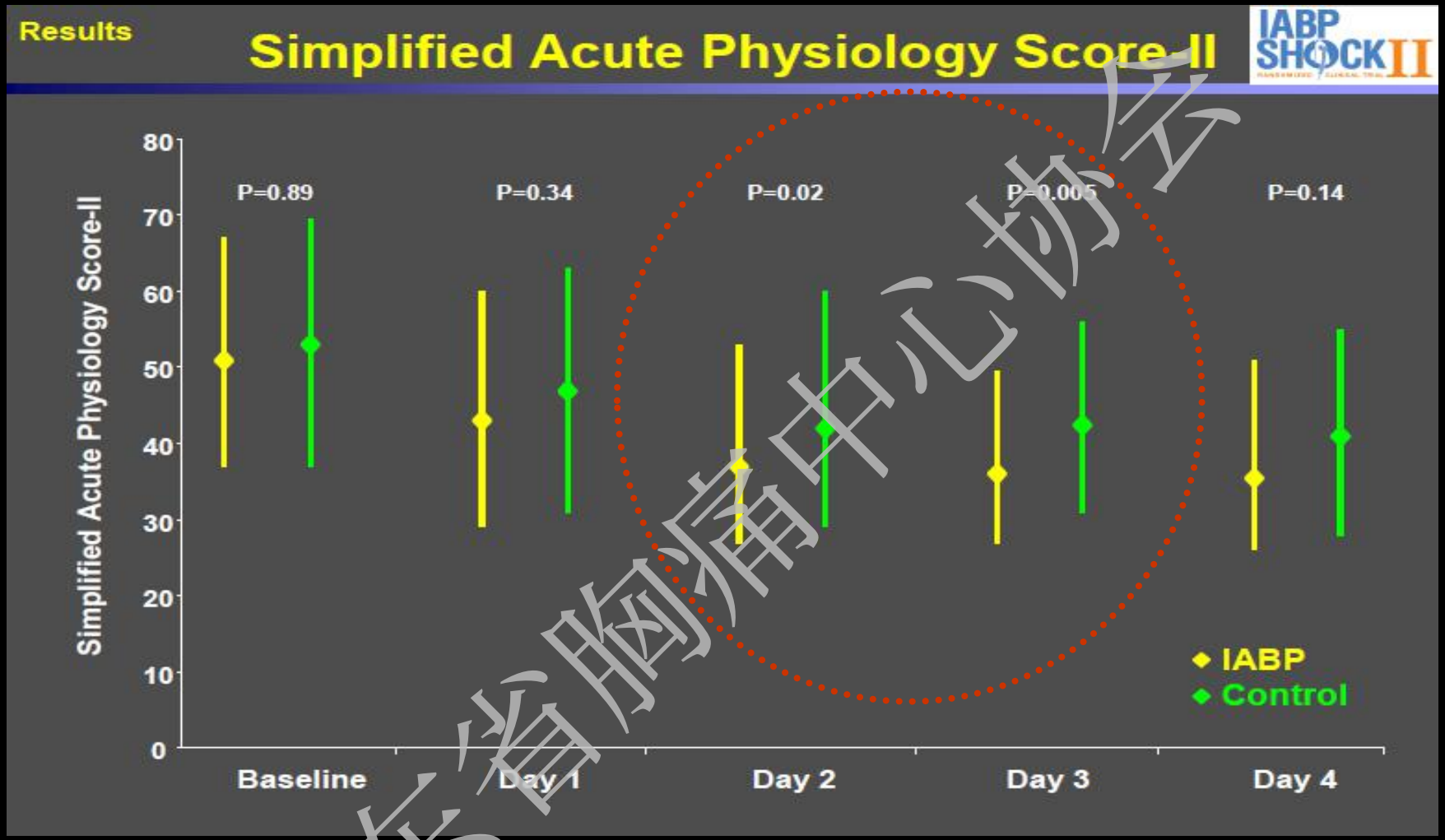
撤机时机：持续时间？

IABP SHOCK 2研究：中位数**3**天（四分位数间距**2-4**），最长**16**天

- 北京朝阳医院：**348**例**IABP**患者（并非都是心源性休克患者），维持时间：**123.8±101.0** 小时

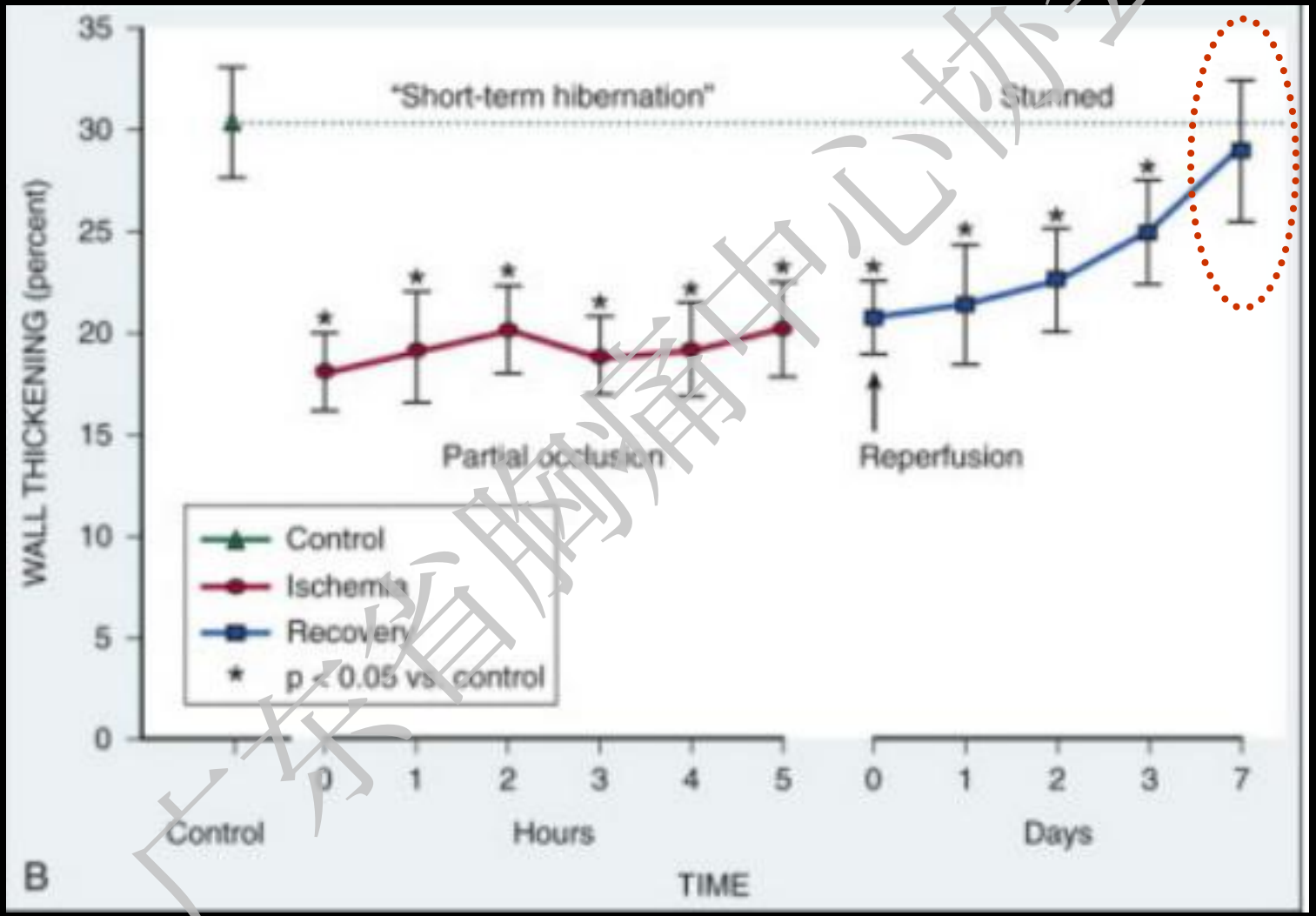
dix. The median duration of intraaortic balloon pump support was 3.0 days (interquartile range, 2.0 to 4.0; range, 1 to 16).





- 术后2天和3天， IABP组反映疾病严重程度的SAPS II积分明显较低，第4天则无差异

顿抑心肌恢复功能需要时间



IABP的何时撤机？

- 呼吸功能正常，血氧改善时先撤除机械通气
- 逐渐减少正性肌力药物用量
- 逐渐降低辅助比率
  - 辅助时间越长，降低辅助比率（ **1:2** ）观察时间需要越长
- 超声，**BNP**动态评估左室功能好转

何时撤机？并无明确定量指标和定论，需要结合临床，个体化操作

临床指标：

- 休克心衰症状，体征改善，末梢循环良好
- 血压相对稳定：
  - 平均动脉压＞**70mmHg**、**SBP**＞**90mmHg**
  - 血管活性药物下调（多巴胺＜**5μg/kg·min**）
- 尿量 ＞**1ml/kg·h**

IABP的何时撤机？

辅助检查指标

- 血液动力学指标改善：（**CI＞2.0L/m2·min，PCWP＜18mmHg**）
- 乳酸下降，酸中毒等内环境紊乱纠正

易发生严重并发症的危险因素

Table 5. Risk Factors for Major Complications of IABP*

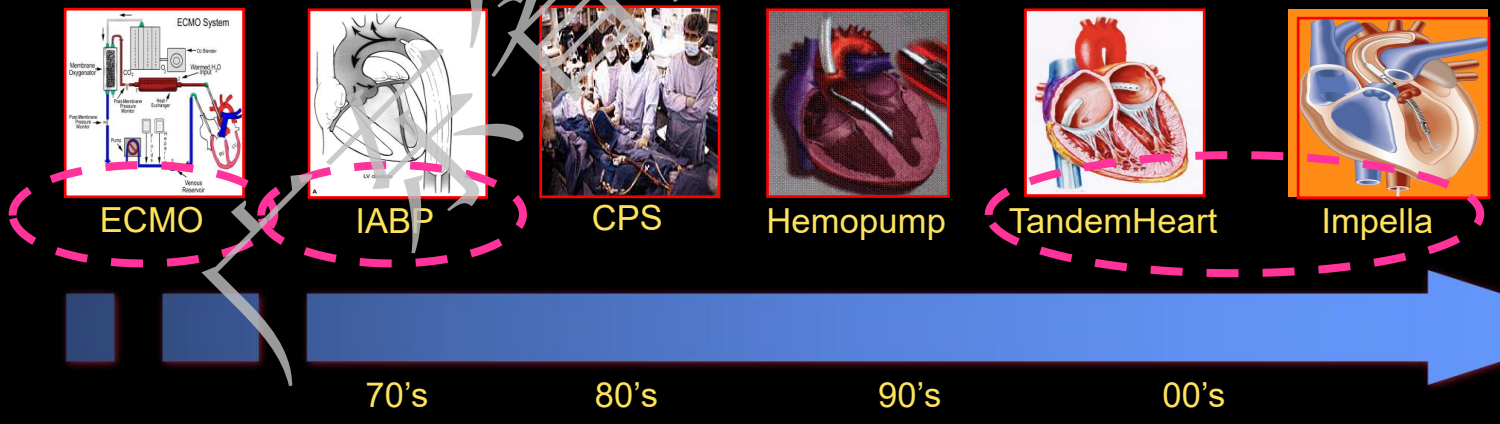
Risk Factor	Estimated Odds Ratio (Presence/Absence)	95% Confidence Limits	p Value
PVD	1.968	1.557, 2.487	<0.001
Female	1.737	1.414, 2.134	<0.001
BSA <1.65 m^2	1.453	1.095, 1.926	<0.05
Age ≥75 yrs	1.289	1.048, 1.585	<0.05

对易发生严重并发症的高危人群，或已经出现严重并发症的患者，应权衡利弊，可适当缩短辅助时间

J Am Coll Cardiol 2001;38:1456–62

理想的循环辅助装置

- **改善周围循环**：维持足够的动脉血压和心输出量，逆转受损的循环功能，恢复周围脏器的组织灌注，促进重要脏器功能恢复。
- **心肌保护**：改善冠脉灌注，降低心脏充盈压力和心肌氧耗，避免心肌缺血加重和坏死进展。



常用循环辅助装置

表 6 常用循环辅助装置重要参数

	IABP	ECMO	Tandem Heart	Impella
辅助机制	气动	离心泵	离心泵	轴流
鞘管外径（F）	7.5-9	18-21（静脉端） 15–22（动脉端）	21（静脉端） 15–17（动脉端）	13-23
插管置入方式	经皮穿刺股动脉	经皮穿刺股动静脉	经皮穿刺股动静脉	经皮穿刺 /外科切开股动脉
床旁置入可能	Y	Y	N	N
置入时间	+	++	++++	++－++++
增加心输出量程度	0.5-1 L/min	>4.5 L/min	3-5 L/min	2.5-5 L/min
心脏后负荷	降低	增加	增加	—
呼吸支持功能	无	有	可能	无
肢体缺血风险	+	+++	+++	++
抗凝要求	+	+++	+++	+
溶血	+	++	++	++
稳定心率要求	Y	N	N	N
术后管理要求	+	+++	++++	++

增加冠脉灌注，减轻心脏后负荷

增加周围组织灌注，改善氧合

增加心脏输出量，增加心脏后负荷

增加心脏输出量，

IABP支持是稳定病人危重情况的暂时手段，对于长时间不能撤机的休克患者（“IABP依赖”）：

- 积极寻找和改变休克原因：
  - 及时血运重建
  - 纠正心包压塞、心律失常、酸中毒 、容量不足等情况
  - 合并严重瓣膜病变或机械并发症，应尽快外科或介入治疗
- 由于IABP增加心输出量低于其他辅助装置，必要时应考虑及时改用或联用其他循环辅助装置（ECMO，LVAD）

IABP应用

- 应用时机：尽早应用，不仅在血管重建术之前，必要时可以考虑在诊断性造影之前置入，以求尽快稳定血液动力学状态，为进一步积极治疗创造条件
- 撤机时间：足够疗程，这样可能有利于部分仍然存活的顿抑心肌逐渐恢复活动，并且可以等待因急性低灌注损伤的全身各系统功能恢复和趋于稳定

Contemporary Management of Cardiogenic Shock

A Scientific Statement From the American Heart Association

ABSTRACT: Cardiogenic shock is a high-acuity, potentially complex, and hemodynamically diverse state of end-organ hypoperfusion that is frequently associated with multisystem organ failure. Despite improving survival in recent years, patient morbidity and mortality remain high, and there are few evidence-based therapeutic interventions known to clearly improve patient outcomes. This scientific statement on cardiogenic shock summarizes the epidemiology, pathophysiology, causes, and outcomes of cardiogenic shock; reviews contemporary best medical, surgical, mechanical circulatory support, and palliative care practices; advocates for the development of regionalized systems of care; and outlines future research priorities.

Sean van Diepen, MD, MSc, FAHA, Chair
Jason N. Katz, MD, MHS, Vice Chair
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Alice K. Jacobs, MD, FAHA
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Ahmet Kilic, MD
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有关循环机械支持治疗

- 目前没有证据指导选择适合机械循环支持的心源性休克患者以及把握治疗时机。建议患者如果出现持续性心源性休克，伴有或不伴有终末器官低灌注，应当考虑使用机械循环支持，并综合多学科专业知识选择、植入和管理相应设备。
- 心源性休克患者伴有急性二尖瓣关闭不全或者室间隔缺损，可以考虑使用**IABP**，同时当其他机械循环支持设备无法使用、有禁忌症或者无法置入时，可以考虑选择性地用于严重心源性休克患者。
- 当心肺复苏过程中或者需要使用一种可替代的临时机械循环支持设备缓慢提高氧合时，可以考虑使用静脉对动脉体外膜肺氧合疗法。

有关综合治疗

- 心源性休克患者，复杂的急性疾病需要多学科治疗团队提供程序操作、外科手术、内科护理，临床手术量同样也与生存率显著相关。
- 移动移动ECMO团队将心源性休克患者转移至指定中心方案合理可行，可以让有需要的患者通过轮辐式网络模型，成功获得早期支持与治疗。
- 三级大型心血管病中心应该建设成为心源性休克接诊中心，每一个心血管医疗系统内，这些中心接受来自低级医疗单位心源性休克患者的转诊，使患者以获得进一步教育和治疗。
- 由双重训练的的心脏病-重症监护医生可能会明显改善预后。CICU治疗环境可能最适合心源性休克患者的中心化心脏护理，但心脏病主治医师及治疗团队可能并未全力投入培训去治疗相关的多器官功能衰竭，而ICU可能更适合处理非心脏器官功能衰竭

期待中国自己的心源性休克专家共识

中国心源性休克临床诊断和治疗专家共识（草案）

心源性休克（cardiogenic shock，CS）是指由于各种原因所致心脏功能减退，引起心输出量显著减少，导致血压下降，重要脏器和组织供血严重不足，引起全身性微循环功能障碍。从而出现一系列以缺血、缺氧、代谢障碍及重要脏器损害为特征的一种临床综合征。近年来，随着临床心血管技术的发展，尤其是急性心肌梗死再灌注治疗的普及，CS 的死亡率有所下降。但 CS 仍然是目前心脏病患者死亡的最主要原因，严重威胁患者生命。同时，在临床 CS 的处理中仍存在一定争议，包括血管活性药物和心肺辅助技术相关临床研究结果的解读，新的临床研究结果和国外指南更新与我国真实临床实践存在一定差异。而目前有关 CS 处理的推荐散见于急性冠脉综合征，经皮冠状动脉介入治疗，心衰处理等相关指南中，我国尚无专门关于 CS 的系统性的指南及专家共识文件。

为促进我国 CS 诊疗的标准化和规范化，提高 CS 救治成功率，降低 CS 患者的病死率，由中华医学会心血管病分会心血管急重症学组牵头，组织国内心血管急重症领域专家制定符合我国临床实践的 CS 临床诊治共识。

更具现实意义的是，目前我国除 IABP 以外的其他机械循环辅助器械远未普及，而且操作复杂，费用昂贵。国内仅有部分大的医学中心常规开展 ECMO 治疗，但 CS 应用经验仍较少。而经皮左室辅助装置（LVAD）更未正式进入我国市场，仅有少数医院极少的试用个例。虽然，理论上新的机械辅助装置增加心输出量优于 IABP，但目前尚无大型随机对照研究比较 IABP 和新型机械辅助装置的临床有效性。有限的资料提示，与 IABP 比较，LVAD 并不能改善 LVEF，也不能降低 30 天和 6 个月死亡率[60-61]。此外，IABP-SHOCK 2 研究也提示，随着器械的改良和临床管理的加强，置入 IABP 是安全的，并不增加并发症的发生[38]。因此，对于常规药物治疗不稳定的 CS 患者仍应考虑置入 IABP，强调尽早使用，合理的适应症选择，以及足够疗程支持。同时，应该积极探讨新的机械辅助装置临床应用，尤其是已经具备 ECMO 条件的医院，需要加强多科合作，扩大在 ECMO 在 CS 患者中的临床应用。

循环辅助装置使用建议
1. 不稳定CS患者应考虑尽快置入机械辅助装置
2. 无ECMO和LVAD条件，应尽快置入IABP，强调早期置入和足够支持时间
3. 鉴于ECMO增加CO优于IABP，有条件医院应考虑置入VA-ECMO，或与IABP合用
4. 有条件的医院可以考虑置入LVAD

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中国IABP治疗注册登记研究

Registry Study of Intra-aortic Balloon Pump in China

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