



CARDIAC SAFETY
RESEARCH CONSORTIUM

September 7, 2018

Outcome Endpoints: Mortality Plus? *Clinical/Best Practice Perspective*

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Mortality is a Great Endpoint, but....

IMPELLA Trials of Cardiogenic Shock

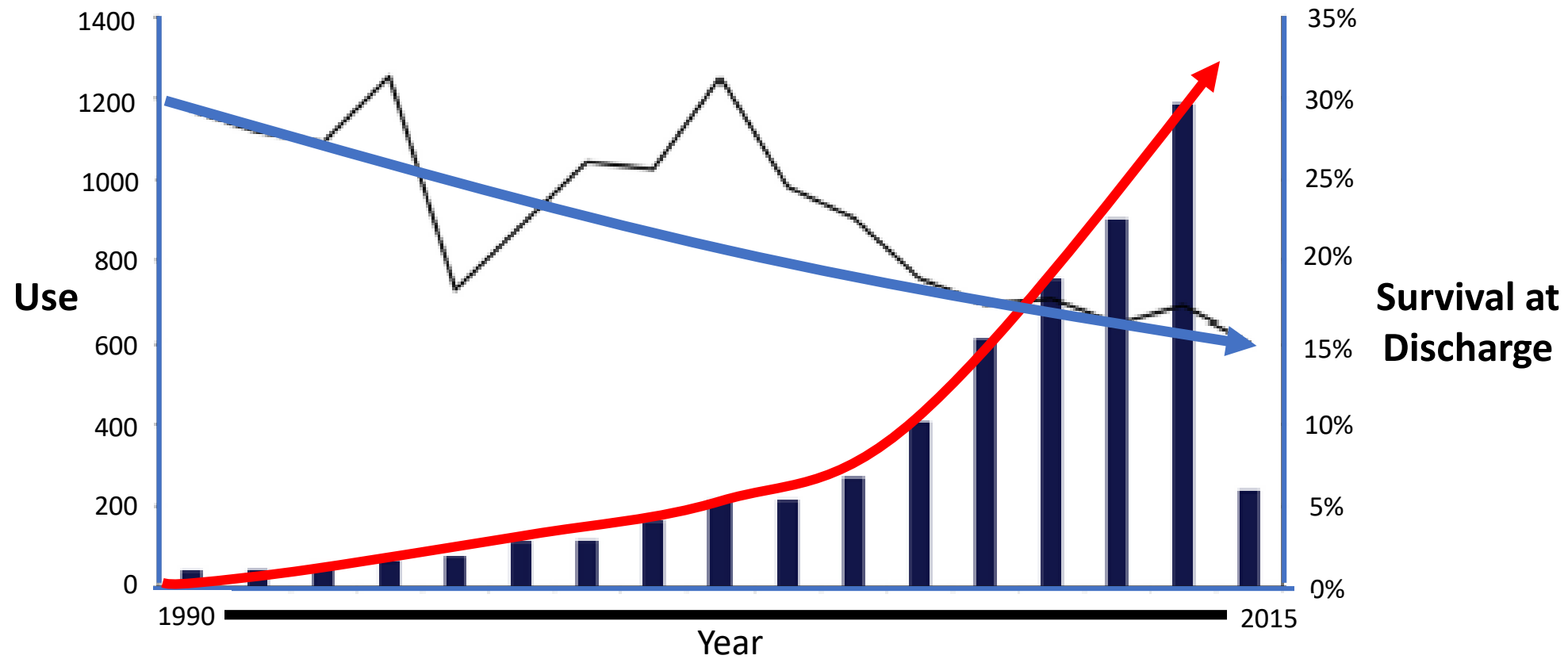
Trial	Enrollment	Comment
FRENCH Trial	19/200	Terminated early
ISAR Shock	26	systematic problems
IMPRESS STEMI	21/130	Terminated early
RECOVER II FDA	1/384	Terminated early
DAN Shock	90/360	Enrolling
IMPRESS Cardiac Arrest	48/48	under powered

Early Termination Common

Slow or futile enrollment

Mortality May not Tell the Whole Story

Temporal Trends in Post-cardiotomy VA ECMO



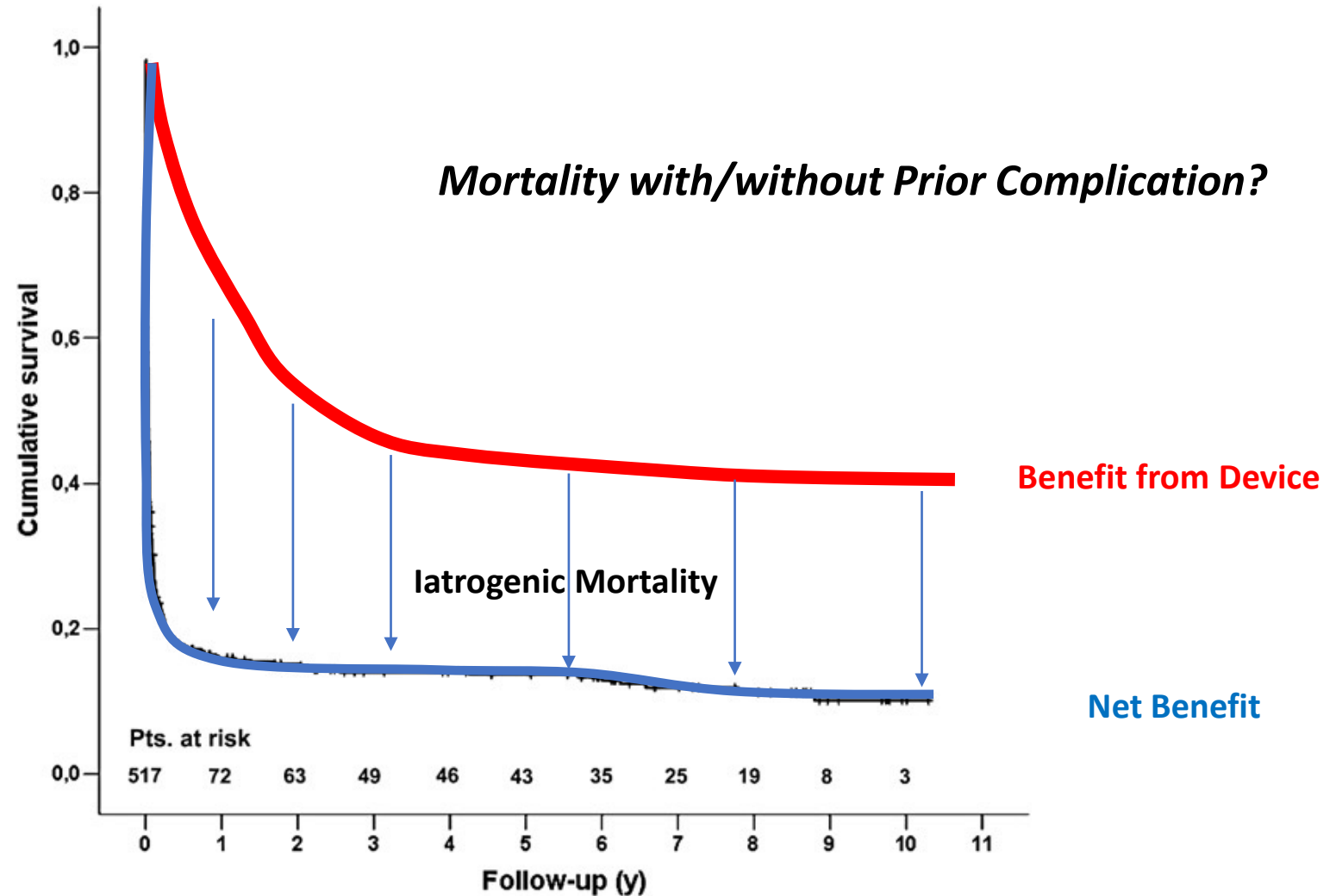
Co-Morbidity



Phase of care	Intraoperative, 40%; postoperative, 60%	
Cannulation	Central, 60%; peripheral, 40%	
ECMO duration	3.3 ± 2.9 d (0-25 d)	
IABP used	74%	
Complications		
Hemorrhage	3100 mL in first 24 h	
Renal failure	65%	
Reoperations	64%	
Gastrointestinal complications	19%	Blood use is associated with bad outcomes
Stroke	17%	
Leg ischemia	20%	
Survival		
Through ECMO	63%	Mortality High
To discharge	25%	
At 6 mo	18%	

Rastan AJ, Dege A, Mohr M, Doll N, Falk V, Walther T, et al. Early and late out-comes of 517 consecutive adult patients treated with extracorporeal membrane oxygenation for refractory postcardiotomy cardiogenic shock. J Thorac Cardio-vasc Surg. 2010;139:302-11.e1.

Iatrogenic Creep





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What Do Patients Want?

Freedom from stroke

Get me home



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Measurable Outcomes

Freedom from Neurologic Event

Freedom from LVAD

Freedom from heart transplantation

Maximum home-time after discharge



Home Time



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Definition: Time spent alive & out of a health care institution

Patient-reported outcome (PRO)

Demonstrated as a robust & easily measured in stroke & recently heart failure

May reflect the burden of disease as experienced by the patient

Fonarow GC, et al. Assessment of home-time after acute ischemic stroke in Medicare beneficiaries. *Stroke* 2016;47:836-42.

Greene SJ, et al. Home-time after discharge among patients hospitalized with heart failure. *JACC* 2018;71: 2643-52.



Clinical Endpoints



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Root-cause of mortality may be a telling endpoint

Iatrogenic device events

Blood product use

Stroke

Outcomes

Freedom from LVAD or transplantation

Home-Time as a PCO

Thank you



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