

Why Consider SSO₂ Therapy?

Acute Myocardial Infarction (AMI) is a leading cause of death in the United States, affecting roughly 790,000 patients each year.¹ Although angioplasty and stenting has been the standard of care in treating heart attacks for 25 years, many patients do not achieve maximum clinical benefit and suffer from reduced heart function. Up to 30% of MI patients develop heart failure² and of those, 50% will die within 5 years.³ Heart failure dramatically impacts patient quality of life⁴ and carries high healthcare costs. Heart failure deaths rose 38% between 2011-2017.⁵ The annual cost of heart failure is expected to rise from \$30B to \$70B by 2030.⁶

SSO₂ Therapy has been shown in multiple randomized prospective clinical trials to consistently and safely reduce infarct size in “widowmaker” heart attack patients.^{7,8,9} Decades of research on heart attack patients has demonstrated that infarct size reduction is correlated with reduced mortality and heart failure, and better left ventricular function.¹⁰

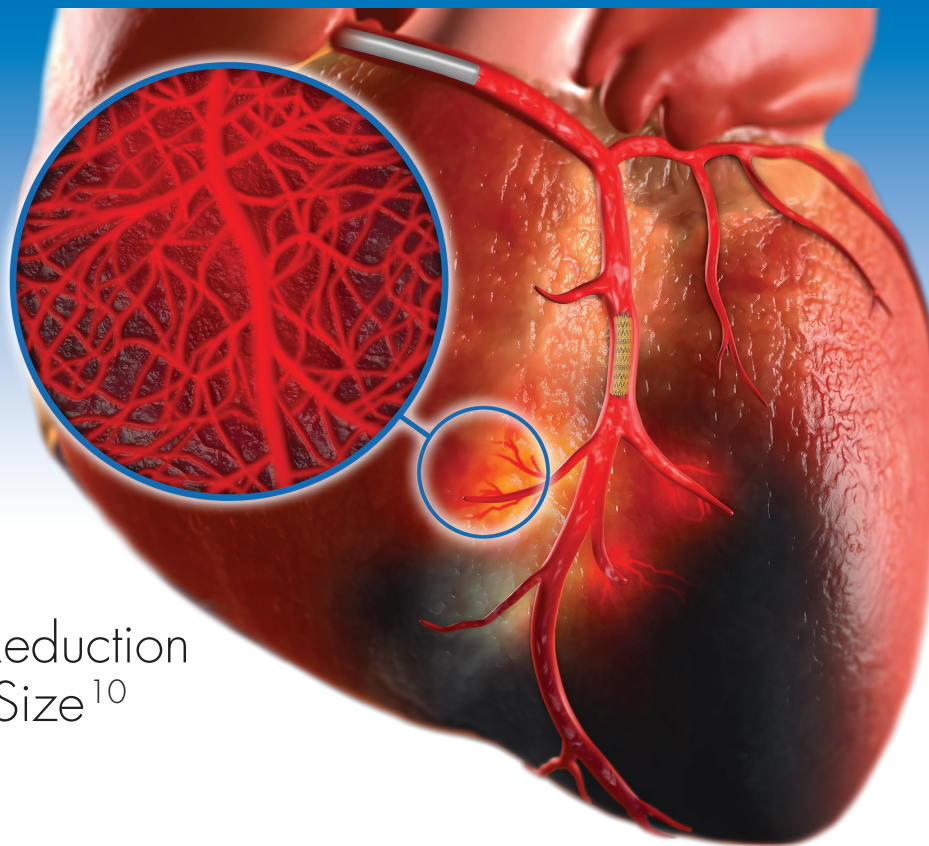
A propensity-score matched analysis comparing similar patients from INFUSE-AMI and the TherOx IC-HOT study was performed to evaluate 1-yr clinical outcomes. Results indicate that adverse events occurred at much lower rates in the IC-HOT study as compared to the similar INFUSE-AMI study. Table 1 presents one-year comparative outcome data.

Event	Statistic	IC HOT (n=83)	INFUSE-AMI (n=83)	Hazard Ratio (95% CI)	P-value
Death	KM (%)	0.0%	7.6%	NA	0.012
Death + HF	KM (%)	0.0%	12.3%	NA	0.001
Reinfarction	KM (%)	0.0%	2.4%	0.97 [0.14, 6.88]	0.97
Target Vessel Revascularization (TVR)	KM (%)	2.4%	5.1%	0.97 [0.14, 2.69]	0.4
Death + HF + Reinfarction + TVR	KM (%)	3.1%	14.8%	0.16 [0.04, 0.7]	0.005

Table 1. Reduced mortality and heart failure at one year in SSO₂ Therapy

SSO₂ Therapy

SSO₂ Therapy involves a one-time 60-minute infusion of the patient's blood, superoxygenated to hyperbaric levels, and administered to the LMCA immediately following PCI <6 hours of symptom onset.



26%
Median Reduction
in Infarct Size¹⁰

¹American Heart Association. Heart Disease and Stroke Statistics, 2017 AHA-Glance.

²Gerber, et al. *JAMA Cardiol.* 2016;1(2):156-162.

³Mozzafarian D, et al. *Circulation.* 2016;133:e38-e360.

⁴Nieminen MS, et al. *Intl Jour of Cardio.* 15 Jul 2015. Vol 191;256-264.

⁵Sidney, et al. Association Between Aging of the US Population and Heart Disease Mortality From 2011 to 2017. *JAMA Card.* Published online 30 Oct 2019.

⁶Heidenreich, et al. Forecasting the Impact of Heart Failure in the United States: A Policy Statement From the American Heart Association. *Circ Heart Fail.* 2013 May; 6 (3): 606-619.

⁷O'Neill WW, et al. *J Am Coll Cardiol.* 2007;50; No.5. 397-405.

⁸Stone GW, et al. *Circ Cardiovasc Interv.* 2; 366-375. Sep 2009.

⁹David SW, et al. *Catheter Cardiovasc Interv.* 2018;1-9.

¹⁰Stone, G.W. et al. *J Am Coll Cardiol.* 2016;67(14):1674-83.

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