ACC Latin America Conference 2017

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GLOBAL EXPERTS, LOCAL LEARNING

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Chief Coronary Care Unit – Sanatorio Finochietto - Argentina

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ACC Latin America Conference 2017

LEVO CTS
levosimendan in cardio thoracic surgery

ACC.17
66th Annual Scientific Session & Expo

Levosimendan In Patients With Left Ventricular Systolic Dysfunction Undergoing Cardiac Surgery With Cardiopulmonary Bypass

PRIMARY RESULTS OF THE LEVO-CTS TRIAL

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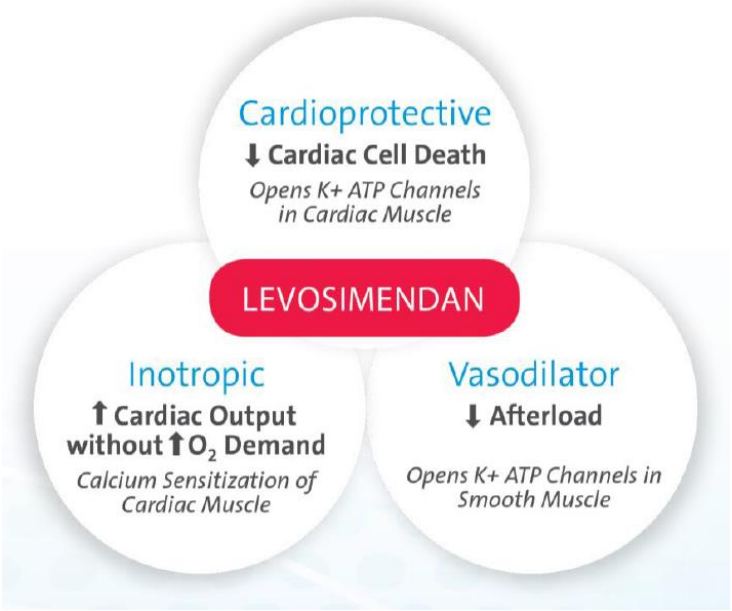
on behalf of the LEVO-CTS Investigators

Background



Levosimendan is not approved by FDA

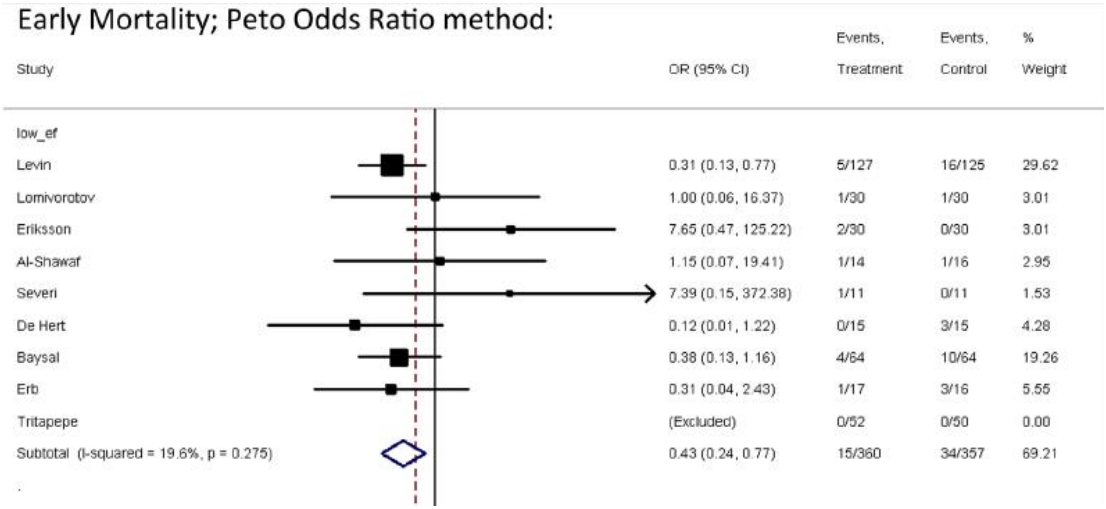
Hemodynamic effects and mortality rates of levosimendan vs dobutamine

Levosimendan	Dobutamine	HR (95% CI)	p value
28%	15%	1.9 (1.1-3.3)	0.022
26%	38%	0.57 (0.34-0.95)	0.029

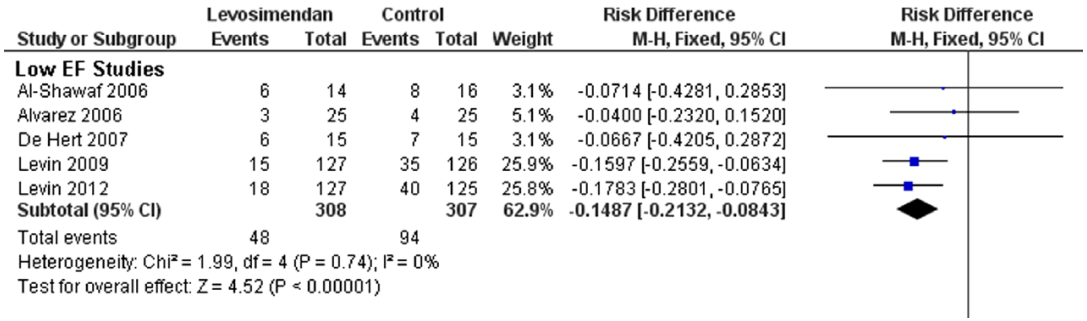
Follath F et al. Lancet 2002, julio 20

Background

Early Mortality



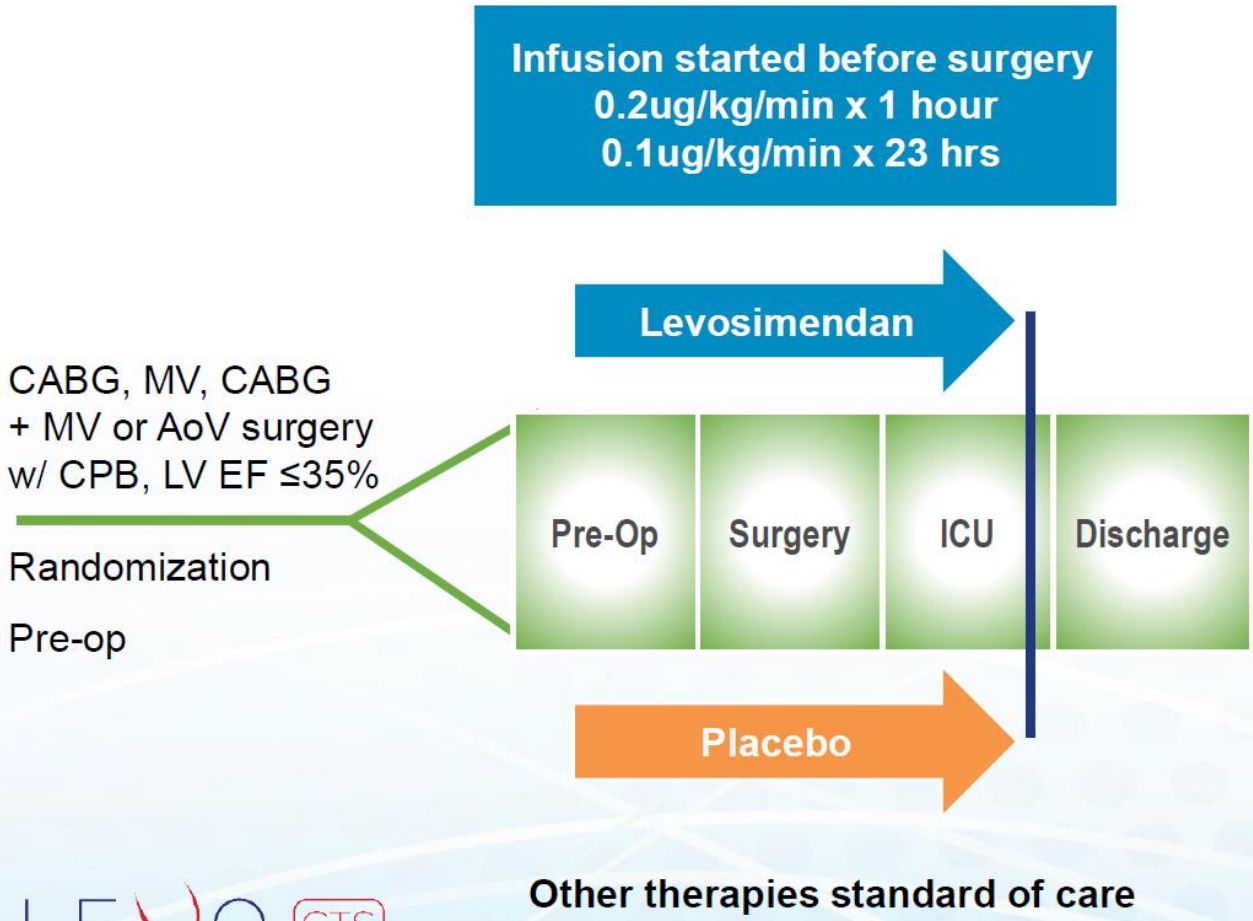
Harrison RW et al . J Cardiothorac Vasc Anesth 2013; 14



Ju Yong Lim et al . J Card Surg 2015; 30

Design

Multicenter, Prospective, Randomized, Double blind, Placebo controlled



Co-primary outcomes*

- **Quad:** death (≤30d), dialysis (≤30d), MI (≤5d), mechanical assist (≤5d)
- **Dual:** death (≤30d), mechanical assist (≤5d)

Secondary outcomes

- Low cardiac output syndrome
- Use of secondary inotropes beyond 24 hr
- ICU length of stay

Safety outcomes

- Hypotension
- Atrial fibrillation
- 90-day vital status

**Analysis of co-primary outcomes adjusted for covariates of age, sex, LV EF, and type of surgery.*

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Mehta RH, et al., Am Heart J 2016;182:62-71

Header

Baseline Characteristics

	Levosimendan n=428	Placebo n=421
Age, median (25th, 75th), years	65 (59, 73)	65 (58, 72)
Female sex	18.9%	21.1%
White race	91.0%	89.5%
LV EF, median (25th, 75th), %	26 (24, 32)	27 (22, 31)
Surgery type		
CABG	66.1%	66.5%
CABG + Aortic valve	8.4%	8.1%
CABG + Mitral valve	11.7%	11.4%
CABG + Mitral + Aortic valve	2.3%	2.4%
Mitral valve	8.4%	7.4%
Mitral + aortic valve	2.3%	3.3%
Aortic valve	0.7%	0.7%

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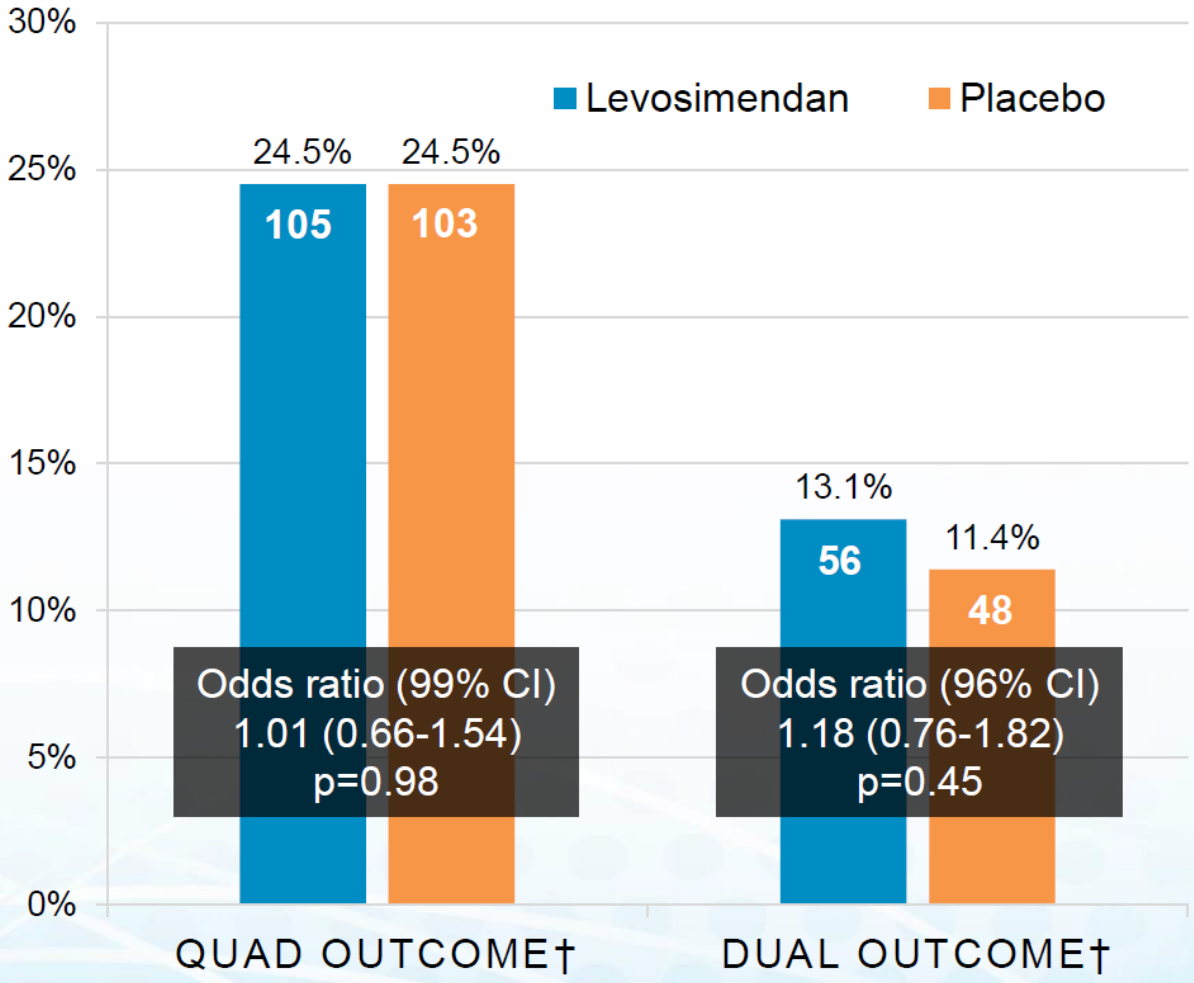
Mehta RH et al. N Engl J Med 2017; 376

Co-Primary Outcomes



Quad Outcome = death, dialysis, MI or mechanical assist device use

Dual Outcome = death or mechanical assist device use

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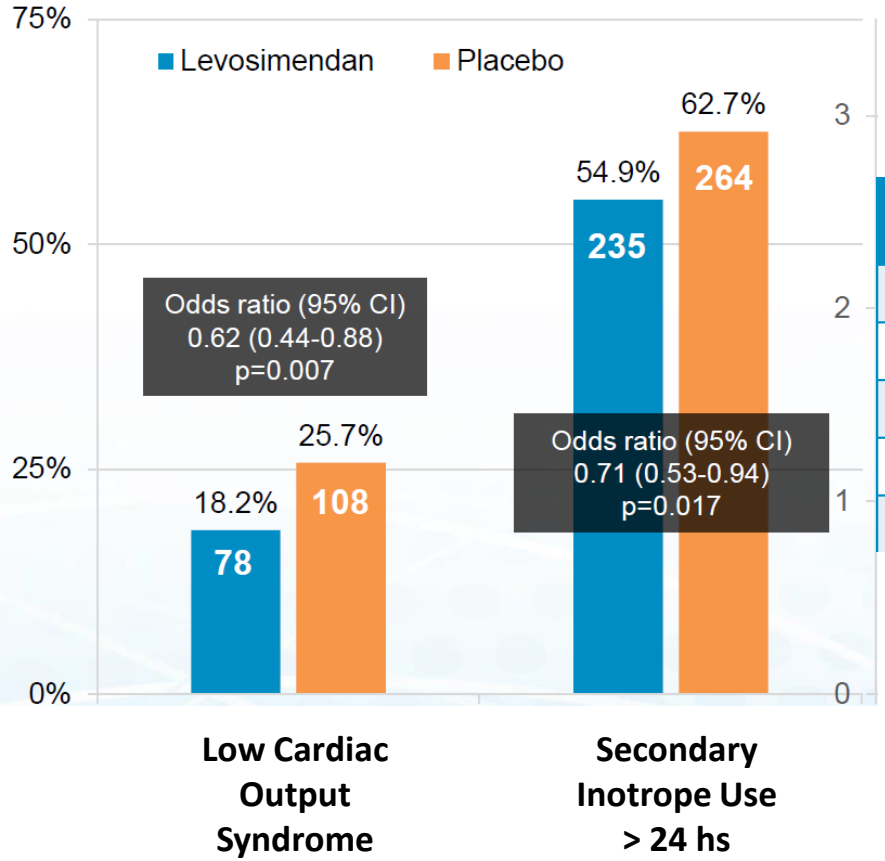
†Adjusted for covariates: type of surgery, LVEF, age, sex

Mehta RH et al. N Engl J Med 2017; 376

Secondary Outcomes



30-Day Safety Outcomes

	Levosimendan n=428	Placebo n=421	p-value
Hypotension	155 (36.2%)	138 (32.8%)	0.29
Atrial fibrillation	163 (38.1%)	139 (33.0%)	0.12
VT / VF	46 (10.7%)	41 (9.7%)	0.63
Stroke	15 (3.5%)	10 (2.4%)	0.33
Rehospitalization	54 (12.6%)	48 (11.4%)	0.55

Mehta RH et al. N Engl J Med 2017; 376

Conclusions

- **Levosimendan**,

given **Prophylactically prior to cardiac surgery**
to patients with **reduced left ventricular function**
Had no effect on the co-primary outcomes of:

- Death, Dialysis, MI or mechanical assist device use
- Death or mechanical assist device use

As an inotrope was **effective and safe** to increase cardiac output

Mehta RH et al. N Engl J Med 2017; 376

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ORIGINAL ARTICLE

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R.H. Mehta, J.D. Leimberger, S. van Diepen, J. Meza, A. Wang, R. Jankowich, R.W. Harrison, D. Hay, S. Fremes, A. Duncan, E.G. Soltesz, J. Luber, S. Park, M. Argenziano, E. Murphy, R. Marcel, D. Kalavrouziotis, D. Nagpal, J. Bozinovski, W. Toller, M. Heringlake, S.G. Goodman, J.H. Levy, R.A. Harrington, K.J. Anstrom, and J.H. Alexander, for the LEVO-CTS Investigators*

Mehta RH et al. N Engl J Med 2017; 376