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# Inotropes and Cardiogenic Shock
## DoReMi Trial

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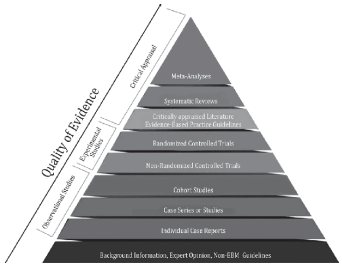
## Evidence Base and the Knowledge Gap

- Cardiology and critical care as fields produce large amounts of low-quality evidence
- Both specialties utilize poorly-justified beliefs to guide therapy of patients in absence of robust data





The only true wisdom is in knowing you known nothing - Socrates

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## Evidence Base and the Knowledge Gap

A thing is not necessarily true because a man dies for it – Oscar Wilde

- NICE sugar – intensive glucose control in ICU – NNH 33 for death
- CAST I trial – suppression of PVCs post MI – NNH of 21 for death
- CAST II trial – suppression of PVCs post MI – NNH of 50 for death
- TTM2 – therapeutic hypothermia post ROSC – NNH 14 for unstable arrhythmia
- PARAMEDIC2 – epinephrine in OHCA – NNH 166 for survival with severe neurological impairment

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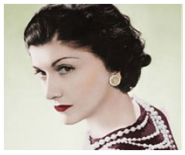
## Evidence Base and the Knowledge Gap



Success is most often achieved by those who don't know that failure is inevitable – Coco Chanel

- **We need guidelines to better reflect uncertainty of recommendations**
  - **Road map of future research**
  - **Help clinicians understand the limitations of current data**
- **We need *randomized* clinical trials that address fundamental beliefs of cardiac/critical care**
  - **The most complex analysis of the largest dataset cannot overcome the power of randomization**
- **We need iterative processes that evaluates evidence and data in context of advancing technology and care**

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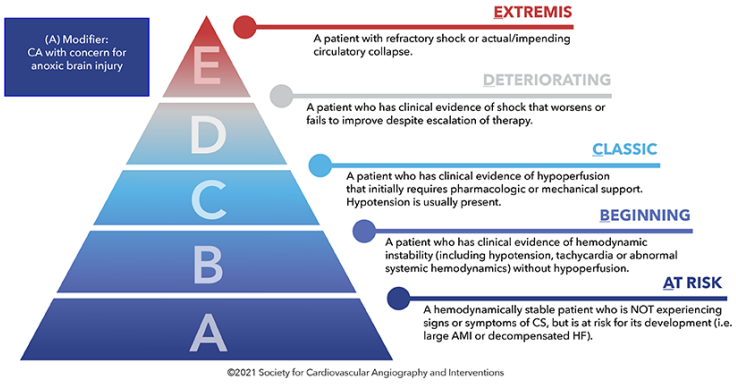
## Cardiogenic Shock

- **Primary cardiac dysfunction leading to critical organ hypoperfusion**
- **Common presentation for both ischemic and non-ischemic HD**
- **High mortality and morbidity**

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Baran et al. 2022

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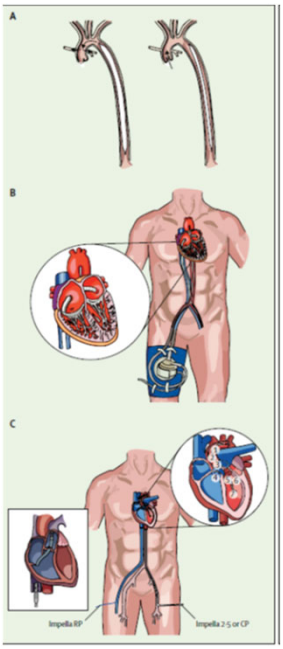
## Cardiogenic Shock

- ***Prognosis altering therapies are limited***
- **Revascularization**
- **Vasopressors**
- **Inotropes**
- **NO-Synthase Inhibitors**
- **MCS**
  - **IABP**
  - **Percutaneous VAD**
  - **ECLS**



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Combes et al. 2020 Lancet

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## Cardiogenic Shock

- **148 studies over 25 years**
- **2.3M patients**
- **In-hospital/30d mortality 36%**

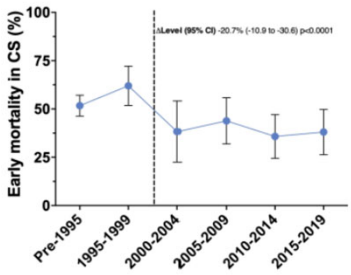


Figure 2. Trends in mortality in cardiogenic shock from 1995 to 2019.

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Jung & Hibbert 2024 *under review*

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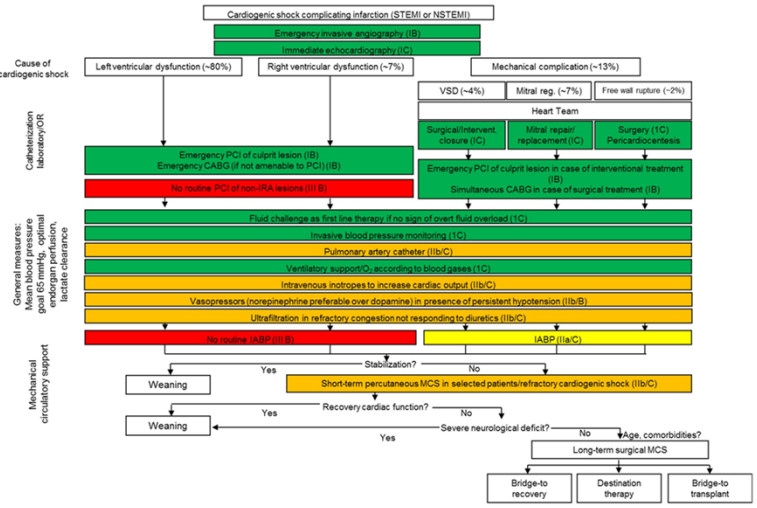
# Cardiogenic Shock

- **Very little data to guide therapy in patients with CS**

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Thiele et al. 2020 EHJ

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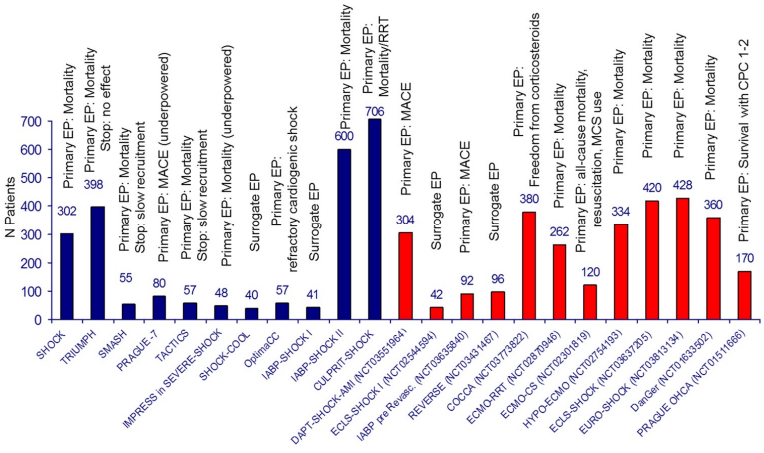
# Cardiogenic Shock

- **DoReMi – 196 patients**
- **ECLS shock – 420 patients**
- **ECMO CS trial – 122 patients**
- **DANGER shock – 360 patients**
- ***RECOVER IV – 560 patients***
- ***DoReMi 2 – 346 patients***

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## Cardiogenic Shock

- The Storm on the Sea of Galilee
  - Rembrandts only sea scape
  - Stolen 1990 in Boston – remains missing
  - Estimated worth 500M

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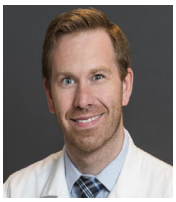
## Objectives

- **Understand the evidence gaps in CS management**
- **Understand the evidence supporting the use of inotropes in CS**
- **Review outcomes of DoReMi trial**
- **Review integration of resident training into running a clinical trial**
- **Future directions**



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## Milrinone & advanced heart failure

- **PROMISE trial**
  - 1088 patients with NYHA III/IV heart failure ambulatory
  - Randomized to milrinone vs. placebo
  - Increase in mortality by 28% - worse in most symptomatic
  - Increase hospitalization, adverse events
- **OPTIME CHF**
  - 951 patients with acute exacerbation of chronic heart failure
  - 48 hour infusion of milrinone or placebo
  - No difference in death or median number of days in hospital
  - Increased hypotension and new atrial arrhythmias


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## Guidelines in Cardiogenic Shock

- ESC
  - IIb – C – continues inotropes may be considered in patients with low output and hypoperfusion as a bridge to MCS or transplant
- ACC/AHA HF
  - IIa – B – Patients with advanced HF who are eligible for and awaiting MCS/transplant – inotrope therapy as bridge is reasonable
  - IIb – B – In select patients who are ineligible for MCS/transplant – as a palliative therapy
  - III – B – In patients with HF – long-term use of either continuous or intermittent for reasons other than above is potentially harmful

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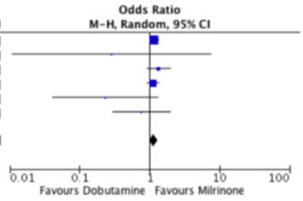
# Background in CS

- Medical management relies on vasopressors/inotropes but prospective, randomized data is lacking
- Milrinone and dobutamine are among the two most widely used agents, but clinical equipoise remains

FIGURE 2A.

| Study or Subgroup | Dobutamine Events | Dobutamine Total | Milrinone Events | Milrinone Total | Weight | Odds Ratio M-H, Random, 95% CI |
|---|---|---|---|---|---|---|
| Abraham, 2005 | 589 | 4226 | 248 | 2021 | 49.3% | 1.16 [0.99, 1.36] |
| Aranda, 2002 | 0 | 19 | 1 | 17 | 0.2% | 0.28 [0.01, 7.40] |
| Arnold, 2006 | 134 | 1311 | 34 | 433 | 10.5% | 1.34 [0.90, 1.98] |
| Hauptman, 2008 | 683 | 8762 | 138 | 1949 | 37.6% | 1.11 [0.92, 1.34] |
| Scroggins, 2005 | 2 | 40 | 5 | 27 | 0.6% | 0.23 [0.04, 1.30] |
| Yamani, 2001 | 21 | 269 | 6 | 60 | 1.9% | 0.76 [0.29, 1.98] |
| **Total (95% CI)** | | **14627** | | **4507** | **100.0%** | **1.13 [1.00, 1.29]** |
| Total events | 1429 | | 432 | | | |

Heterogeneity: Tau² = 0.00; Chi² = 5.42, df = 5 (P = 0.37); I² = 8%
Test for overall effect: Z = 1.89 (P = 0.06)




Forest plot of in-hospital mortality with dobutamine versus milrinone inotrope therapy.

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Mathew et al. 2019 CIM

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# CAPITAL Do-Re-Mi

- **Milrinone versus Dobutamine in the Treatment of Cardiogenic Shock**
- ***Mathew, R.*, Di Santo, P.*, Jung, R., Marbach, J., Hutson, J., Simard, T., Ramirez, F.D., Harnett, D.T., Merdad, A., Almufleh, A., Weng, W., Abdel-Razek, O., Fernando, S.,*** Kyeremanteg, K., Bernick, J., Wells, G.A., Chan, V., Froeschl, M., Labinaz, M., Le May, M., ***Russo, J.,*** Hibbert, B.

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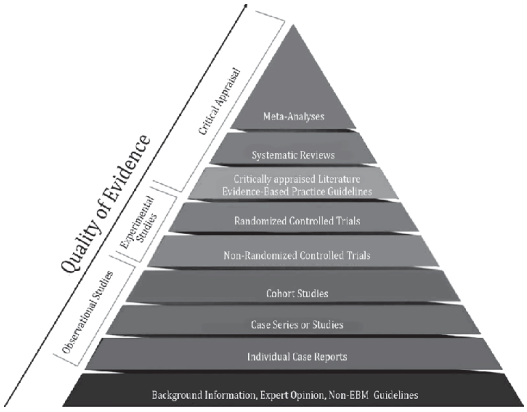
# Methodology

- Randomized clinical trial, with blinding of both physicians and patients
- Stratified by LV/BiV versus RV dysfunction
- Drug titration by clinical evaluation
- Composite primary end point of:
  - *All cause in-hospital mortality*
  - *Resuscitated CA*
  - *Need for transplant or MCS*
  - *Non-fatal MI*
  - *TIA or stroke*
  - *New initiation of RRT*

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# Secondary Outcomes

- **Efficacy**
  - Individual components of primary outcome
  - Total time on inotropes
  - Need for, and total days on, NIV and/or IMV
  - Incidence of AKI
  - Normalization of lactate
  - Arrhythmia requiring medical team intervention
- **Safety**
  - Arrhythmia requiring medical intervention
  - Need for, or an increase, in oral or IV anti-arrhythmic therapy
  - Ventricular arrhythmias
  - Need for, or an increase, in vasopressor therapy

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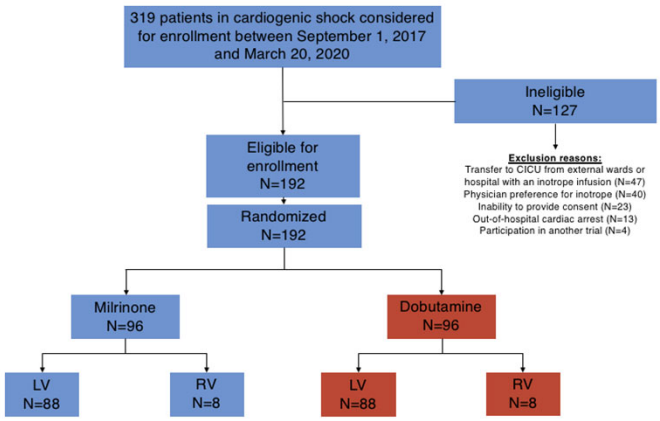
# Results

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# Results

- Patients reflected population
- Average age 70
- Predominantly white, male
- LVEF 25%
- 92% SCAI C,D shock

Table 1. Baseline Characteristics of the Participants.*

| Characteristic | Milrinone (N=96) | Dobutamine (N=96) | |
|---|---|---|---|
| Age — yr | 68.9±13.8 | 72.0±11.3 | ★ |
| Female sex — no. (%) | 36 (38) | 34 (35) | |
| Median body-mass index (IQR)† | 26.4 (23.7–31.0) | 26.0 (22.5–30.5) | |
| Race — no. (%)‡ | | | |
| White | 86 (90) | 79 (82) | ★ |
| Non-White | 10 (10) | 17 (18) | |
| Left ventricular function | | | |
| Median left ventricular ejection fraction (IQR) — % | 25 (20–40) | 25 (20–40) | ★ |
| Cause of ventricular dysfunction — no. (%) | | | |
| Ischemic | 66 (69) | 62 (65) | |
| Nonischemic | 30 (31) | 33 (34) | |
| Coexisting conditions — no. (%) | | | |
| Previous myocardial infarction | 39 (41) | 29 (30) | |
| Previous percutaneous coronary intervention | 30 (31) | 19 (20) | |
| Previous coronary-artery bypass grafting | 20 (21) | 19 (20) | |
| Previous stroke or transient ischemic attack | 13 (14) | 15 (16) | |
| Atrial fibrillation | 49 (51) | 46 (48) | |
| Chronic kidney disease§ | 38 (40) | 40 (42) | |
| Chronic liver disease | 6 (6) | 7 (7) | |
| Chronic obstructive pulmonary disease | 11 (11) | 14 (15) | |
| SCAI cardiogenic shock class — no. (%)¶ | | | ★ |
| A | 0 | 0 | |
| B | 6 (6) | 5 (5) | |
| C | 77 (80) | 78 (81) | |
| D | 10 (10) | 12 (12) | |
| E | 3 (3) | 1 (1) | |
| Time from admission to the cardiac ICU to randomization — hr | 23.4±92.6 | 17.9±50.6 | |

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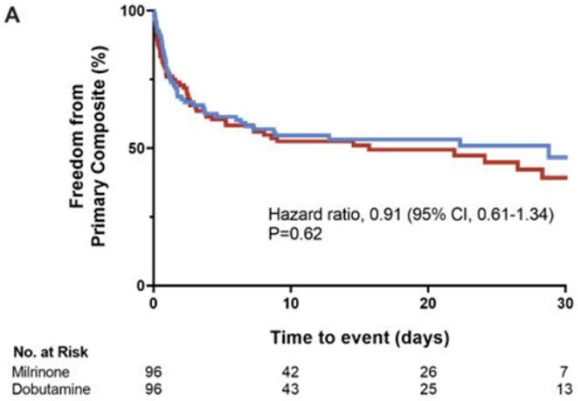
# Primary composite outcome

47 (49%) in milrinone versus 52 (54%) in dobutamine (RR 0.90; CI 0.69-1.19; *P*=0.47)

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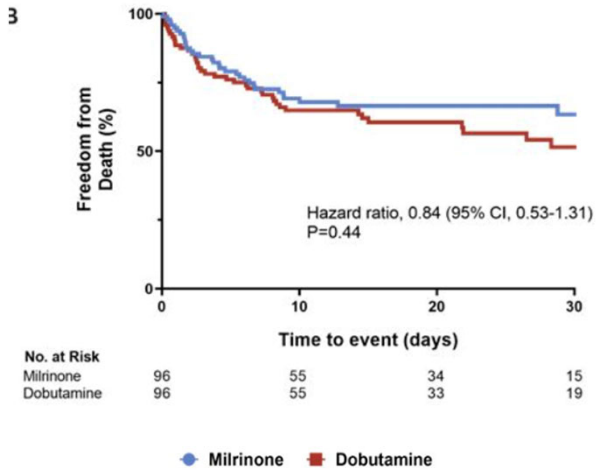
# All-cause in-hospital mortality

35 (37%) in milrinone versus 41 (43%) in dobutamine (RR 0.85; CI 0.60-1.21; *P*=0.38)

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# Secondary outcomes

- No difference in any outcome measured

**Table 2. Primary and Secondary Outcomes.***

| Outcome | Milrinone (N=96) | Dobutamine (N=96) | Relative Risk or Hazard Ratio (95% CI)† | P Value‡ |
|---|---|---|---|---|
| Primary outcome: composite of in-hospital death from any cause, resuscitated cardiac arrest, receipt of cardiac transplant or mechanical circulatory support, nonfatal myocardial infarction, transient ischemic attack or stroke diagnosed by a neurologist, or initiation of renal replacement therapy — no. (%) | 47 (49) | 52 (54) | 0.90 (0.69–1.19) | 0.47 |
| Secondary outcomes | | | | |
| In-hospital death from any cause — no. (%) | 35 (37) | 41 (43) | 0.85 (0.60–1.21) | |
| Resuscitated cardiac arrest — no. (%) | 7 (7) | 9 (9) | 0.78 (0.29–2.07)§ | |
| Receipt of cardiac transplant or mechanical circulatory support — no. (%) | 11 (12) | 14 (15) | 0.78 (0.36–1.71)§ | |
| Nonfatal myocardial infarction — no. (%) | 1 (1) | 0 | — | |
| Transient ischemic attack or stroke — no. (%) | 1 (1) | 2 (2) | 0.50 (0.05–5.50)§ | |
| Initiation of renal replacement therapy — no. (%)¶ | 21 (22) | 16 (17) | 1.39 (0.73–2.67)§ | |
| Median cardiac ICU length of stay (IQR) — days‖ | 4.5 (2.0–7.0) | 5.5 (3.0–10.0) | — | |
| Cardiac ICU length of stay ≥7 days — no. (%)‖ | 31 (32) | 42 (44) | 0.74 (0.51–1.07) | |
| Median hospital length of stay (IQR) — days‖ | 16 (6–28) | 15 (6–27) | — | |
| Median total time receiving inotropes (IQR) — hr‖ | 36 (18–79) | 39 (19–64) | — | |
| Receipt of noninvasive or invasive mechanical ventilation after randomization — no. (%) | 6 (6) | 7 (7) | 0.86 (0.30–2.46) | |
| Median total time receiving noninvasive or invasive mechanical ventilation (IQR) — hr‖ | 48 (6–120) | 48 (12–120) | — | |
| Acute kidney injury — no. (%)¶ | 86 (92) | 85 (90) | 1.02 (0.94–1.12) | |
| Normalization of lactate level — no. (%)** | 33 (46) | 36 (56) | 0.80 (0.56–1.15) | |
| Arrhythmia leading to medical team intervention — no. (%)‡ | 48 (50) | 44 (46) | 1.19 (0.85–1.57) | |

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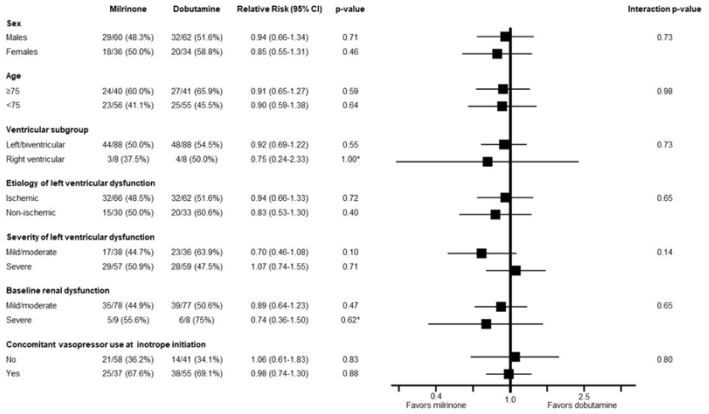
# Results

- No identified subgroup with divergent results

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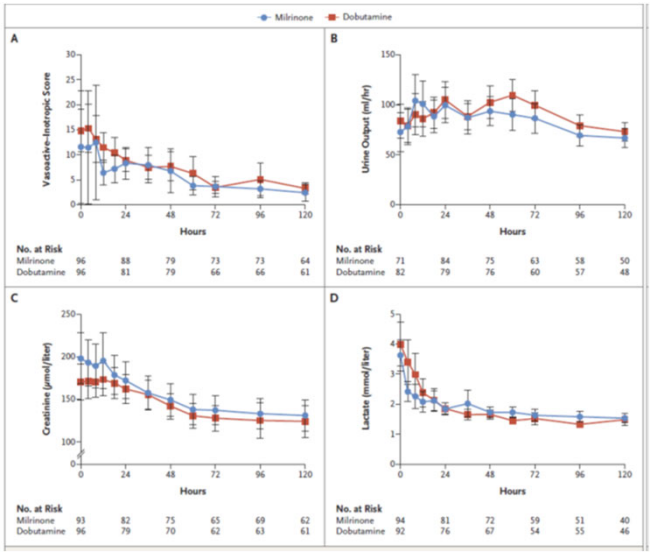
# Hemodynamic outcomes and biomarkers

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# Limitations

- Only in-hospital outcomes were evaluated and differences in outcomes may exist beyond the index hospitalization, as seen in the SHOCK trial
- Our study was designed to be pragmatic, and replicate clinical practice, in which shock is most often defined clinically, rather than hemodynamically
- Our study found a mortality rate of 40%, which is similar to trials that used hemodynamic parameters for enrollment

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# Conclusions

- We were unable to demonstrate a difference between Milrinone and Dobutamine in the primary composite outcome or in important secondary outcomes
- Selection of inotropes could reasonably be based on physician comfort, cost and response to therapy

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# CAPITAL Do-Re-Mi


- **Milrinone versus Dobutamine in the Treatment of Cardiogenic Shock**
- ***Mathew, R.*, Di Santo, P.*, Jung, R., Marbach, J., Hutson, J., Simard, T., Ramirez, F.D., Harnett, D.T., Merdad, A., Almufleh, A., Weng, W., Abdel-Razek, O., Fernando, S.,*** Kyeremanteg, K., Bernick, J., Wells, G.A., Chan, V., Froeschl, M., Labinaz, M., Le May, M., ***Russo, J.,*** Hibbert, B.

The NEW ENGLAND JOURNAL of MEDICINE

American Heart Association. Resuscitation Science

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# BB use and inotrope selection

- **Impact of baseline beta-blocker use on inotrope response and clinical outcomes in cardiogenic shock: a subgroup analysis of the DOREMI trial**

- ***Di Santo P., Mathew, R., Jung, R., Simard, T., Skanes, S., Mao, B., Ramirez, F., Marbach, J., Abdel-Razek, A., Motazedian, P., Parlow, S., Boczar, K.,*** D'Egidio, G., Hawken, S., Bernick, J., Wells, G.A., Dick, A., So, D.Y., Glover, C., ***Russo, J.,*** Mc Guinty, C., Hibbert, B.

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# Background

- Classic teaching and some observational data suggests Milrinone may be preferred in patients on BB
- ESC guidelines recommend against Dobutamine if BBs have been used

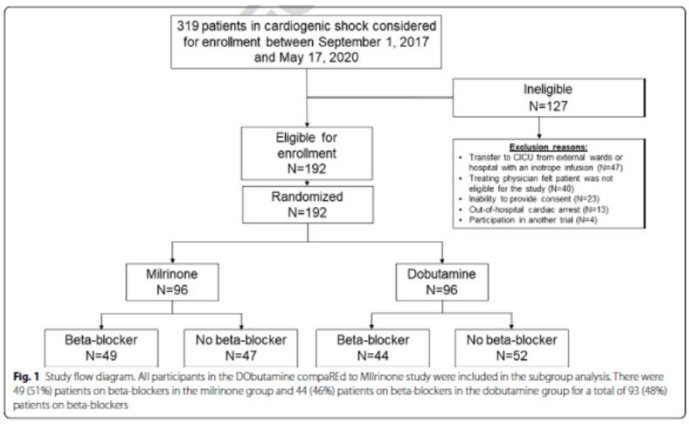


**Fig. 1** Study flow diagram. All participants in the DObutamine compaREd to Milrinone study were included in the subgroup analysis. There were 49 (51%) patients on beta-blockers in the milrinone group and 44 (46%) patients on beta-blockers in the dobutamine group for a total of 93 (48%) patients on beta-blockers

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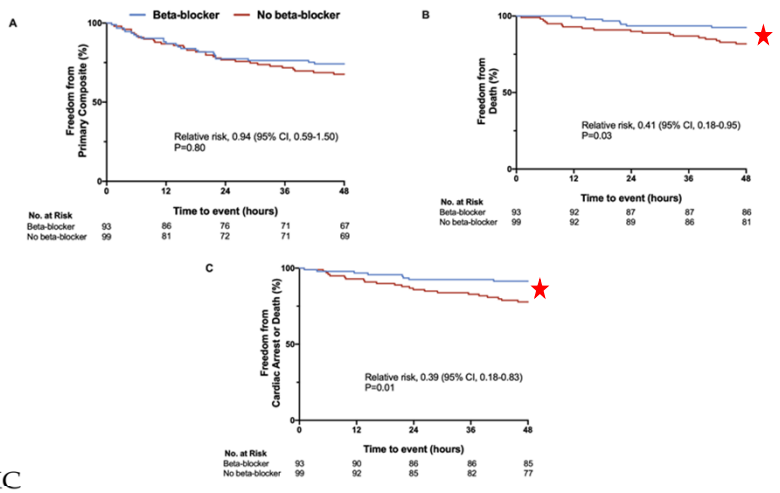
# Clinical outcomes

**Primary composite outcome, mortality and cardiac arrest**

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# Conclusions

- BB therapy in the preceding 24hrs to developing CS was *protective* from cardiac arrest and death in the early resuscitation period
- BB therapy was not predictive of response to inotrope therapy either in hemodynamic or clinical parameters
- Modulating arrhythmic risk in CS may offer mechanisms to reduce adverse outcomes in CS patients

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Di Santo et al. 2021 Crit Care

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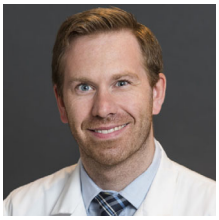
# Biomarkers and outcomes

- **Lactate Clearance as a surrogate for mortality in CS: Insights from the DOREMI trial**

- ***Marbach, J., Di Santo, P.,*** Kapur, K., Thayer, K., ***Simard, T., Jung, R., Parlow, S., Abdel-Razek, O., Fernando, S.,*** Labinaz, M., Froeschl, M., ***Mathew, R.,*** Hibbert, B.



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# Background

- Risk stratification with selection of high-risk biomarkers for CS patients can be used clinically for therapy augmentation and in research as validated surrogates
- Lactate clearance has been suggested as a potential therapeutic target for CS management, but validation studies are few
- Unclear if inotrope selection preferentially impacts LC in populations of CS

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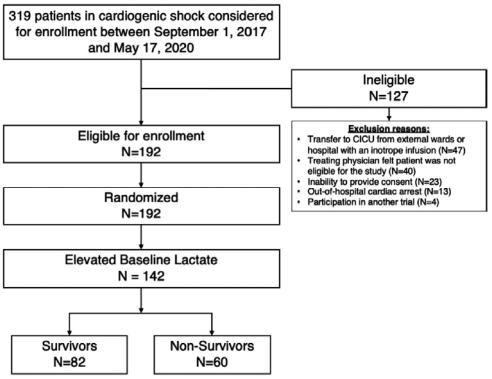
# Results

- 75% of patients had a baseline lactate available before initiation of therapy
- Clinical characteristics differed between survivors and non survivors
  - Higher MAPs
  - Age
  - Less mechanical ventilation
  - Vasoactive agents use was lower amongst survivors but when adjusted for where no longer predicitive

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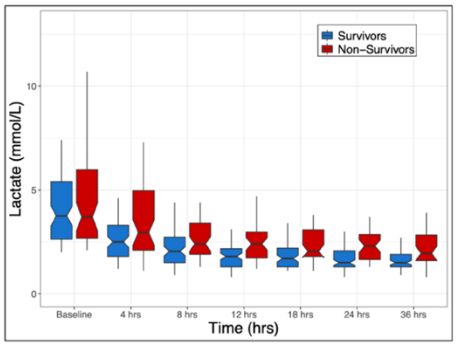
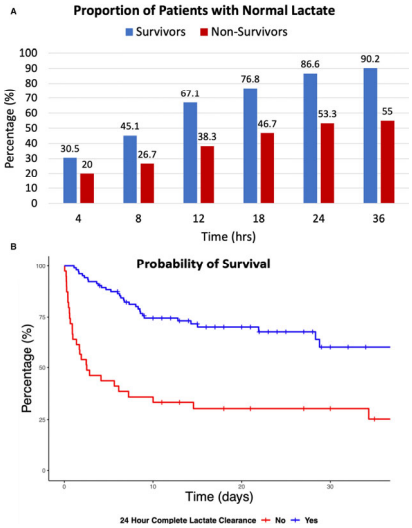
# Results

- MV model strongest predictor of mortality at all time points out to 24 hours – lactate clearance

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# Conclusions

- LC is a strong independent predictor of survival at all time points from 8-36 hours.
- Complete lactate normalization by 8 hours increases chance of survival 4-fold
- Lactate normalization/clearance may be used as a surrogate end-point in exploratory studies for early CS therapies

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Marbach et al. JAHA 2022

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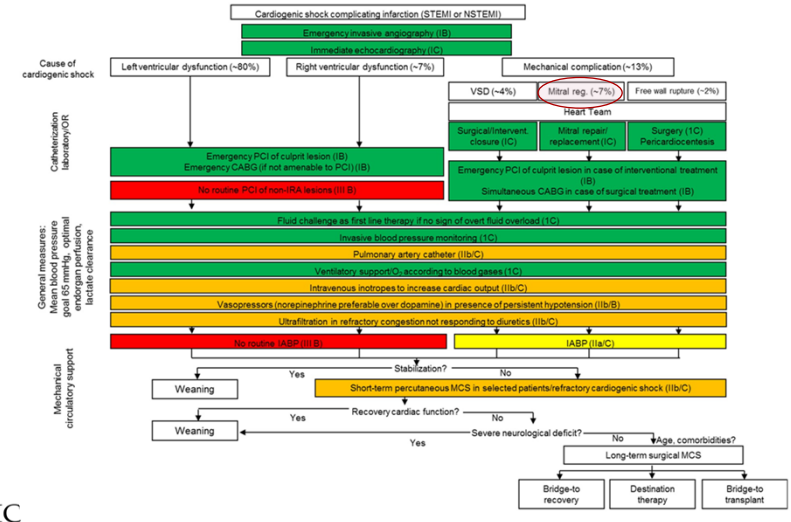
# Valvular HD and CS

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# Valvular HD in CS

- **Significant valvular dysfunction and outcomes in cardiogenic shock: a substudy of the DOREMI trial**
- ***Parlow, S., Weng, W., Di Santo, P., Jung, R., Simard, T., Goh, CY,*** Chan, V., Labinaz, M., Froeschl, M., ***Mathew, R.,*** Hibbert, B.

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Parlow et al. 2022 CJC

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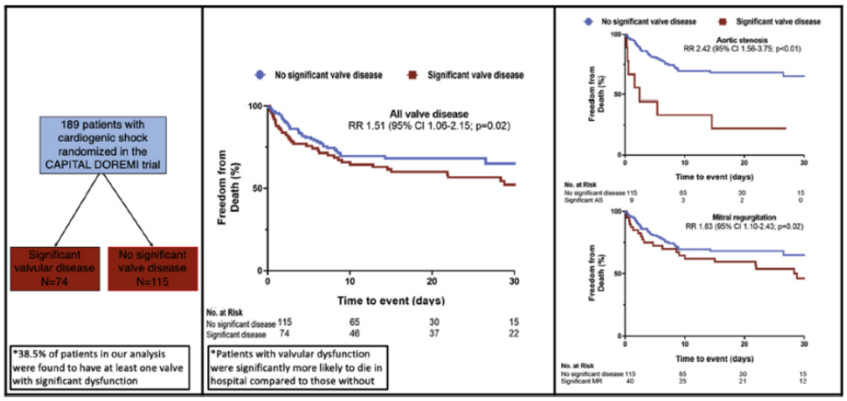
# Valvular HD and CS

- Concomitant valvular lesions in patients with CS is common
  - 40% of patients in CS had one significant valvular lesion
  - 5% significant AS, 21% significant MR, 17% significant TR

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Parlow et al. CJC 2022

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# Conclusions

- Valvular HD is common in unrestricted populations of CS
- Presence of significant AS or significant MR is associated with a 2-fold and 60% increased risk of mortality
- Valve disease is a potential novel therapeutic target in CS

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# Lessons learned from DoReMi

- Pragmatic trials in “difficult” populations can be run in a low cost/high yield fashion
- Fundamental questions in critical care cardiology should be addressed despite prior beliefs
- Integrating residents in trial development and execution is a high yield endeavor

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# MR as a therapeutic target in CS

NEW RESEARCH PAPERS

STRUCTURAL

## Transcatheter Mitral Valve Repair in Cardiogenic Shock and Mitral Regurgitation

### A Patient-Level, Multicenter Analysis

Richard G. Jung, BSc,[a,b,*] Trevor Simard, MD,[a,b,c,*] Christopher Kovach, MD, MSc,[d,e] Kelsey Flint, MD,[d,f] Creighton Don, MD,[e] Pietro Di Santo, MD,[a,c] Marianna Adamo, MD,[g] Luca Branca, MD,[g] Francesca Valentini, MD,[g] Tomás Benito-González, MD,[h] Felipe Fernández-Vázquez, MD, PhD,[h] Rodrigo Estévez-Loureiro, MD, PhD,[i] Alessandra Berardini, MD,[j] Nicolina Conti, MD,[j] Claudio Rapezzi, MD,[k,l] Elena Biagini, MD,[j] Simon Parlow, MD,[a,c] Risa Shorr, MLIS,[m] Amos Levi, MD,[a,c] Ana Manovel, MD,[n] Rosa Cardenal-Piris, MD,[n] Jose Diaz Fernandez, MD,[n] Mony Shuvy, MD,[o] Dan Haberman, MD,[p] Alessandra Sala, MD,[q] Mohamad A. Alkhouli, MD,[r] Claudia Marini, MD,[s] Marta Bargagna, MD,[s] Davide Schiavi, MSc,[t] Paolo Denti, MD,[t] Sinisa Markovic, MD,[u] Nicola Buzzatti, MD,[b] Vincent Chan, MD,[v] Mark Hynes, MD,[w] Thierry Mesana, MD, PhD,[y] Marino Labinaz, MD,[a,c] Federico Pappalardo, MD,[z] Maurizio Taramasso, MD, PhD,[a,y] Benjamin Hibbert, MD, PhD[a,b,c]

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Jung & Simard et al. JACC CI 2021

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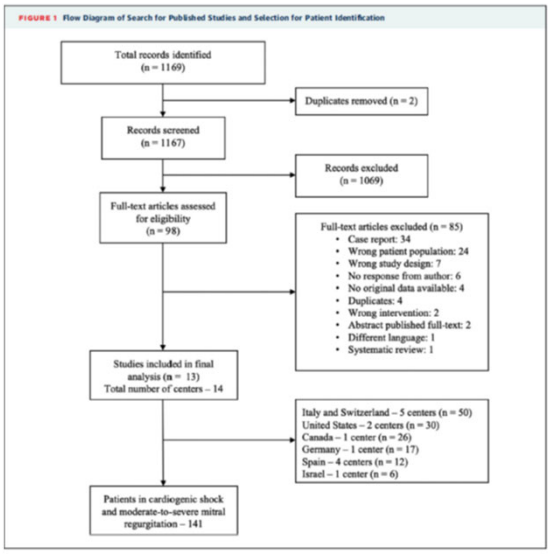
# Results

- Age 70 years
- 87% SCAI C-E
- Predominantly male
- Individual patient data on 141

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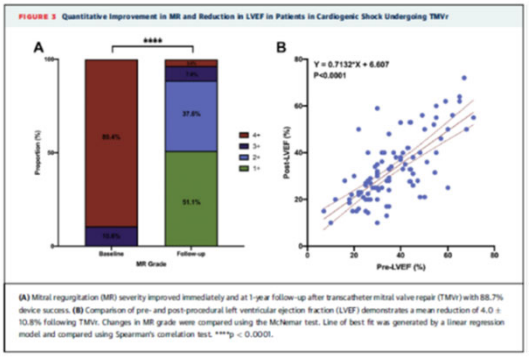
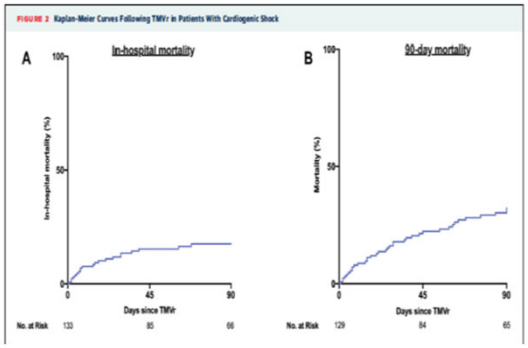
# Results

- In hospital mortality of 15.6%, 90 day mortality 29.5%

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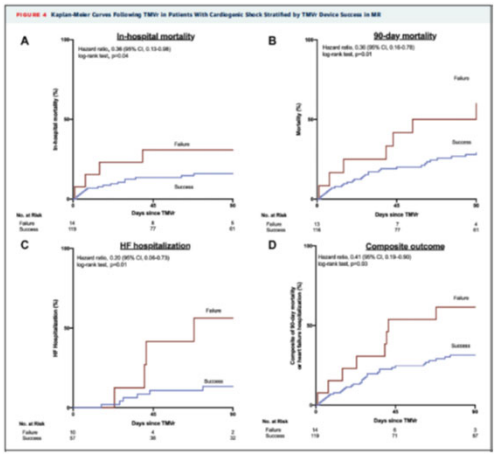
# Results

- MR reduction strongly associated with improved outcomes
- Differences may exist between patients in whom MR reduction can be achieved and in those in whom it cannot
- Efficacy was excellent (device success 87% - 2+ or less) and no adverse procedural events noted

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# Mitral regurgitation as a therapeutic target

- **TEER**
  - **TVT registry tracks cases in USA**
  - **Reports baseline characteristics**
  - **Reports procedural outcomes**

**Transcatheter Edge-to-Edge Mitral Valve Repair in Patients With Severe Mitral Regurgitation and Cardiogenic Shock**

Trevor Simard, MD,[a] Sreek Vemulapalli, MD,[b,c] Richard G. Jung, MD, PhD,[d] Andrew Vekstein, MD,[b,c] Amanda Stebbins, MS,[b,c] David R. Holmes, MD,[a] Andrew Czarnecki, MD, MSc,[e] Benjamin Hibbert, MD, PhD,[d] Mohamad Alkhouli, MD[a]

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Simard et al. JACC 2022

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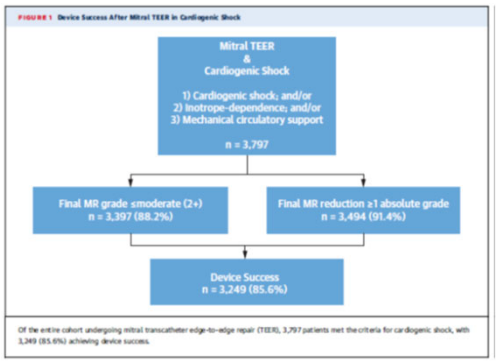
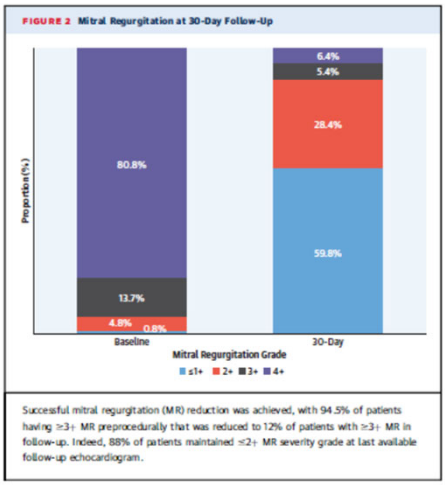
# MR and TEER – TVT analysis




Successful mitral regurgitation (MR) reduction was achieved, with 94.5% of patients having ≥3+ MR preprocedurally that was reduced to 12% of patients with ≥3+ MR in follow-up. Indeed, 88% of patients maintained ≤2+ MR severity grade at last available follow-up echocardiogram.

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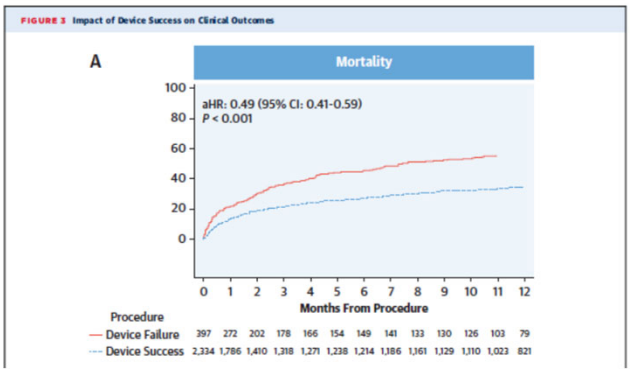
# MR and TEER – TVT analysis

- **TEER in CS**
  - **In-hospital mortality of 9.1% vs. 16.4% in case of device failure**
  - **By 1 year 20% absolute reduction in mortality with procedural success**

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# Conclusions

- Mitraclip therapy in selected patients is safe with no major procedural complications and has similar efficacy to other treated populations
- Observed mortality is significantly lower than expected and successful MR reduction is strongly associated with improved outcome
- A better procedural outcome is predictive of better clinical outcome
- A randomized clinical trial is needed to confirm these findings

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Simard et al. JACC 2022

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# Future Directions

- DOREMI – 2
  - Multicenter trial of inotrope vs. placebo in the early resuscitation of stage C/D cardiogenic shock
  - Establish safety/necessity of inotropes in CS
- MINOS
  - Multicenter trial of mitraclip for stage C/D shock in patients with >/= 3+ MR

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# DoReMi -2

- DOREMI – 2 (n – 346)
  - Inotrope (mil or dob) vs. placebo in initial resuscitation – 12 hours
  - Inclusion criteria
    - SCAI C/D shock and over 18 years of age
  - Exclusion criteria
    - OHCA
    - On inotrope in preceding 24 hours
    - Severe obstructive valve lesion/dynamic outflow obstruction
- Primary Outcome
  - All cause mortality in hospital *or* sustained hypotension, lactate >3.5 at 6 hours, need for MCS, arrhythmia leading to emergent CV or cardiac arrest

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# MINOS trial

- MINOS ( n- 144)
  - Mitraclip vs. standard of care in patients with SCAI C/D shock and 3+ or greater MR
  - Inclusion criteria
    - SCAI C/D shock
    - Or unable to wean inotrope/ventilator support
  - Exclusion criteria
    - Revascularization in preceding 48 hours
    - Degenerative MR and surgical candidate
    - Prior intervention on mitral valve/IE or left sided mass/thrombus
- Primary Outcome
  - In hospital all cause mortality, transplant, implantation of durable LVAD or discharge on palliative inotropes

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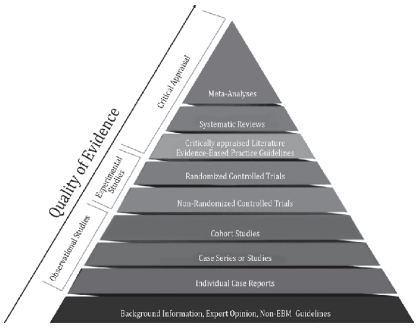
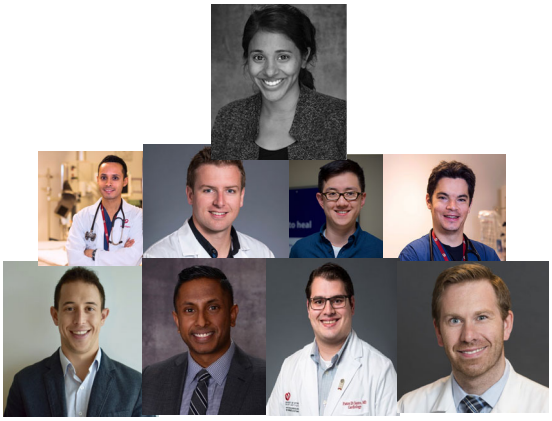
# Questions?



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