CARDIOLOGY 2022 | Children's Hospital of Philadelphia®

Inclusion & Exclusion Criteria for Heart Transplantation after VAD Implantation

David Luís Simón Morales, MD
Professor of Pediatrics and Surgery
Clark-Helmsworth Chair
Director, Congenital Heart Surgery - Heart Institute
Director, Quality and Outcomes - Department of Surgery
Cincinnati Children's Hospital Medical Center

Cincinnati Children's™ changing the outcome together

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VADs as a Bridge to Transplant: When to Stay on the Bridge and When to Exit?

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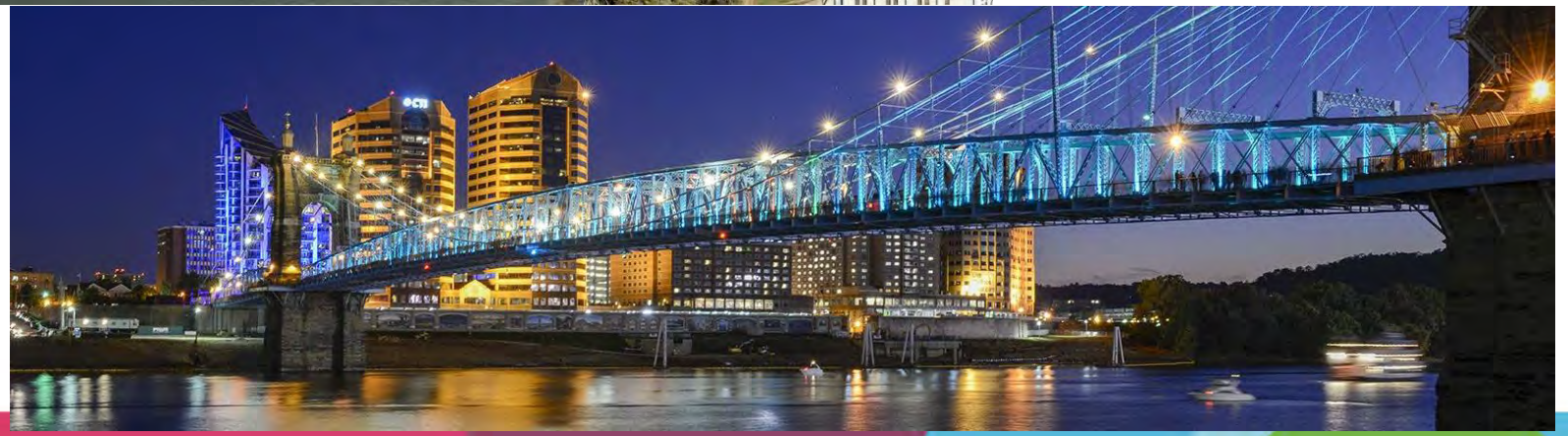
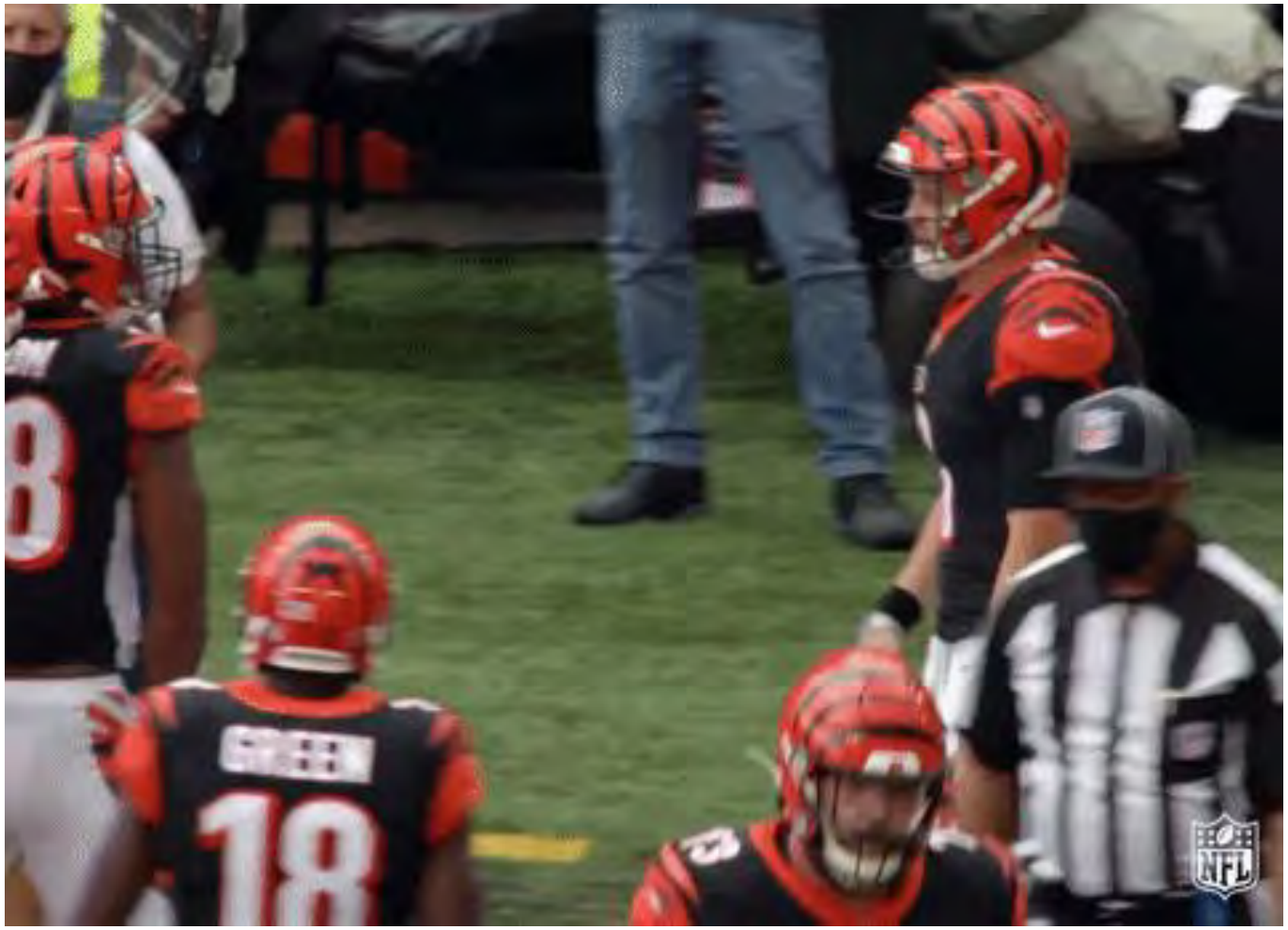
Cincinnati is all about bridges…

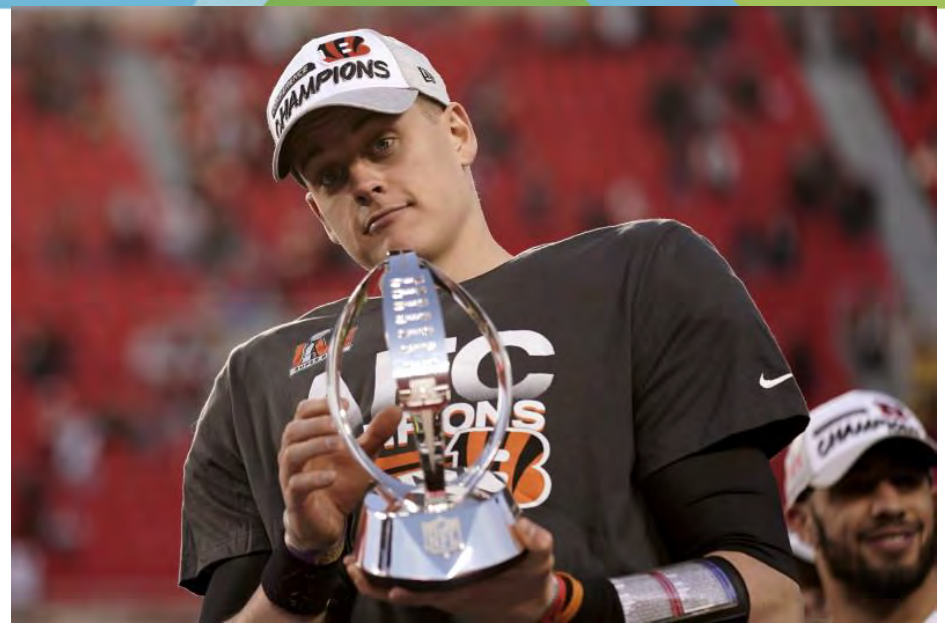

METAL
BRIDGE
DECK



You don’t just take the bridge to get to Cincy…

You don’t just take the bridge to get to Cincy… You take it to have a fun time and be successful!





First playoff win since 1991 and we won the AFC championship

The same is true of transplant

The same is true of transplant

The goal is not just to *get to* transplant…

The same is true of transplant

The goal is not just to *get to* transplant… but to live many years with good health after transplant

In 2004, >35% of kids died waiting for heart transplants

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So at first, we were just happy for a bridge to get us there b/c they were not so sturdy

In 200 for
heart t

So at fi bridge
to get u

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The learning curve was steep w/ VADs…

In 2004, >35 waiting for heart transp

So at first, w y for a bridge to get us the

And the lear teep…

But now our VAD BTT are sturdier and more technologically advanced

The bridge can also be quite long

(Danyang-Kunshan Grand Bridge, Beijing, China)

(102 miles long)

FONTAN VAD 3 yrs

ACHD VAD 10yrs

VAD 11 to 22yo

How Sturdy are our VAD bridges?

Current Landscape of VAD Therapy

- Rates of VAD implantation continue to increase across the U.S.

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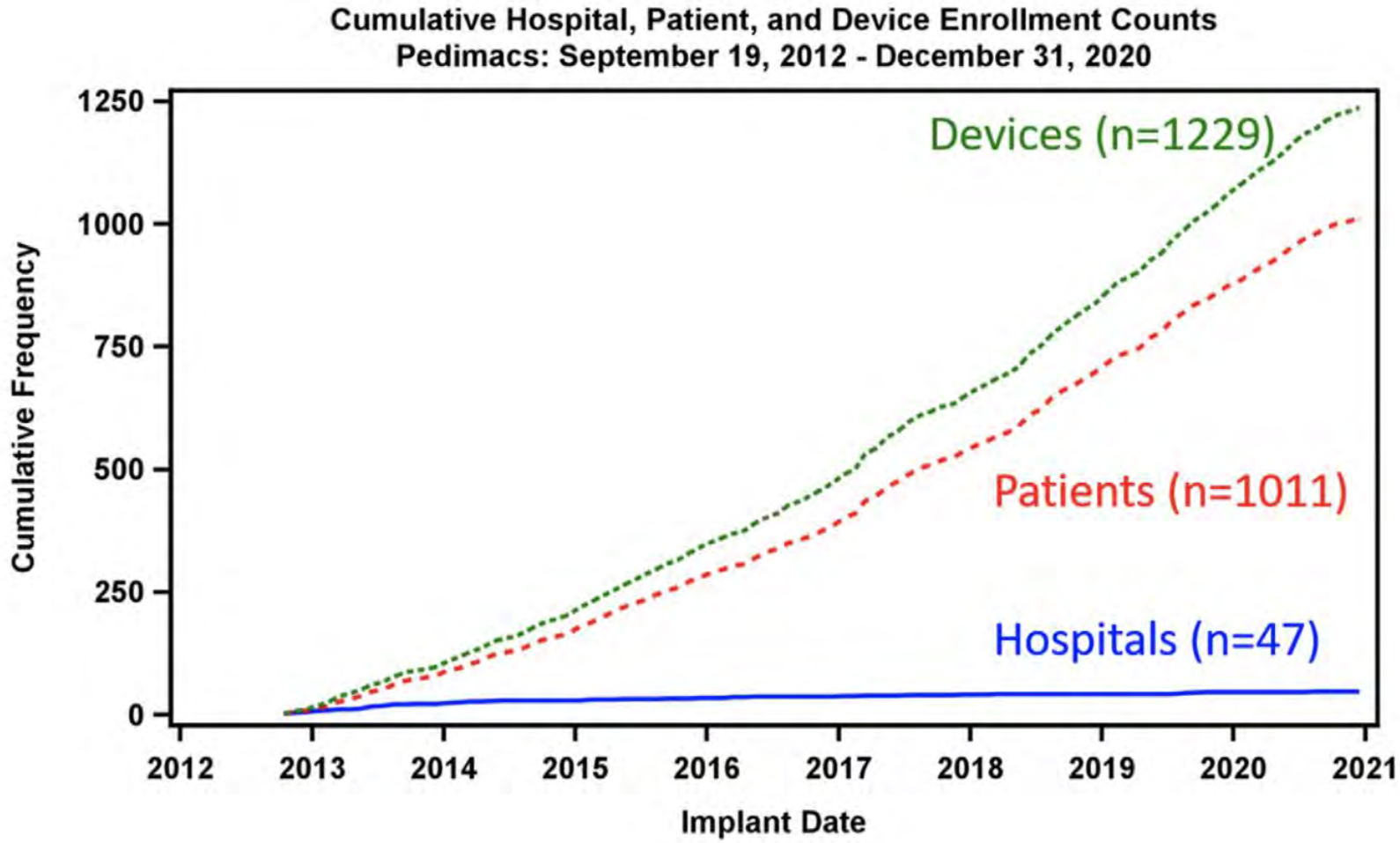

Fifth Annual Pedimacs Report (Rossano & Morales, *et al.* – 2022)

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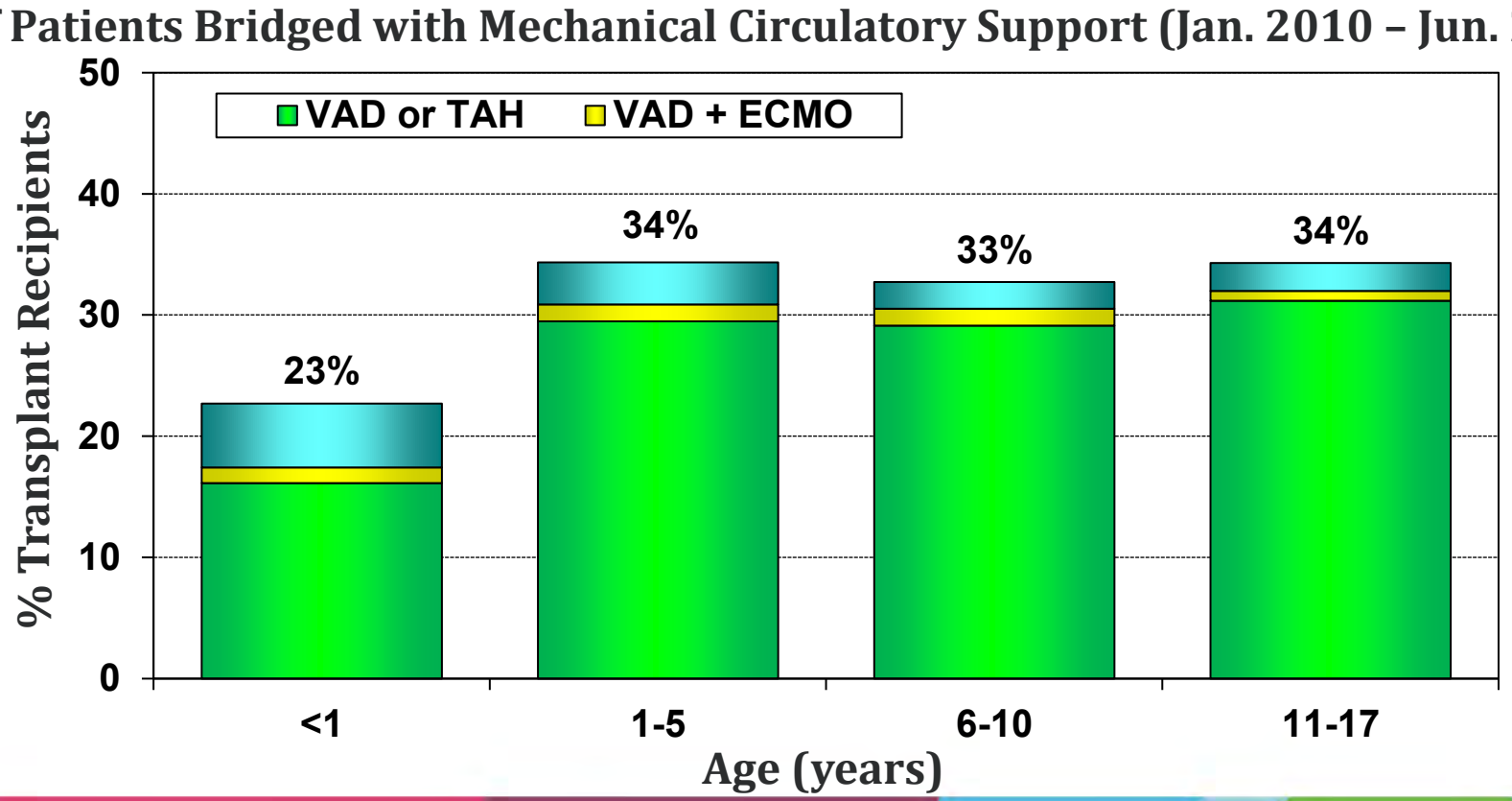
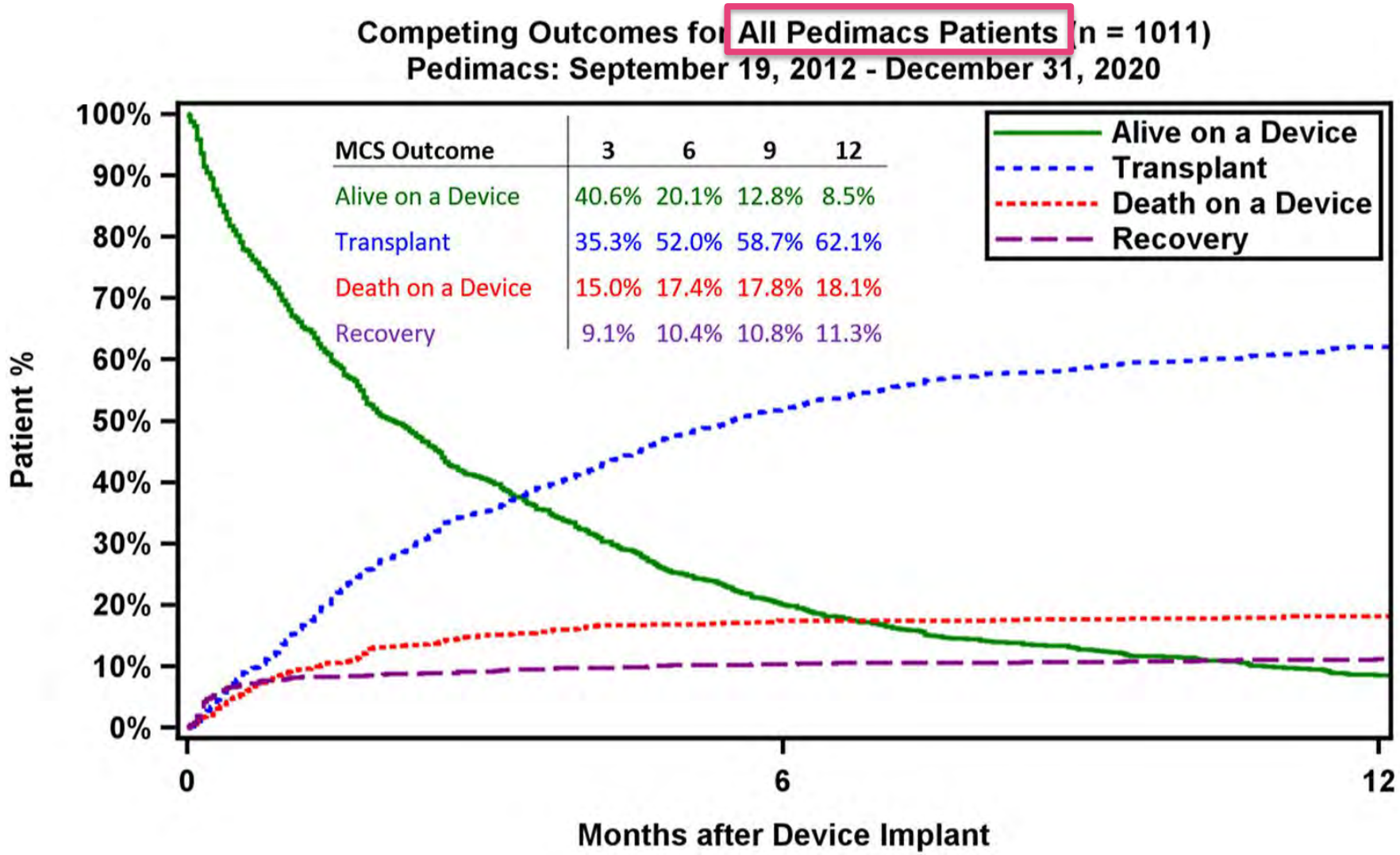


Khush, et al. JHLT (2019)

Current Landscape of VAD Therapy



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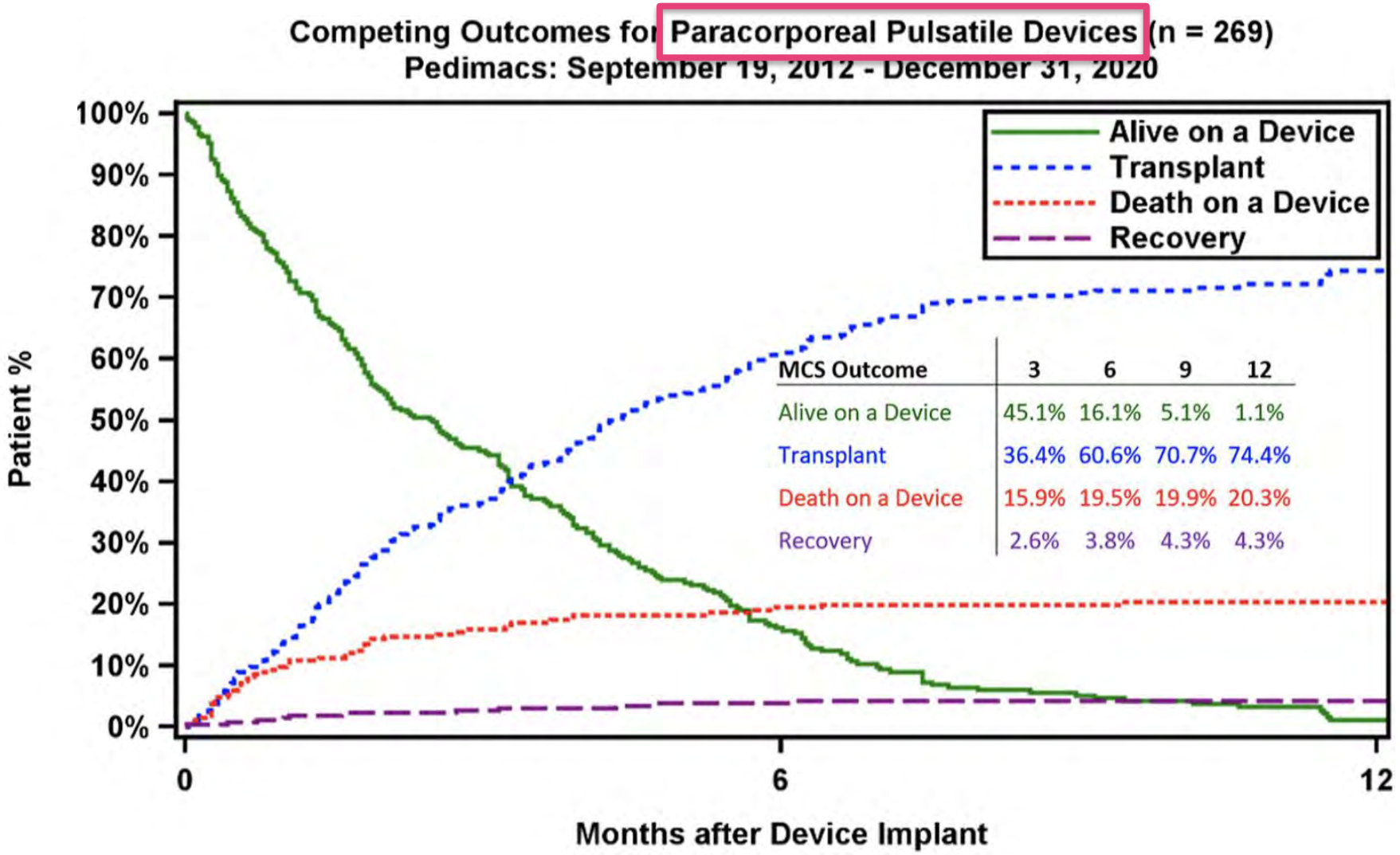
83% of patients achieve a positive outcome

Current Landscape of VAD Therapy



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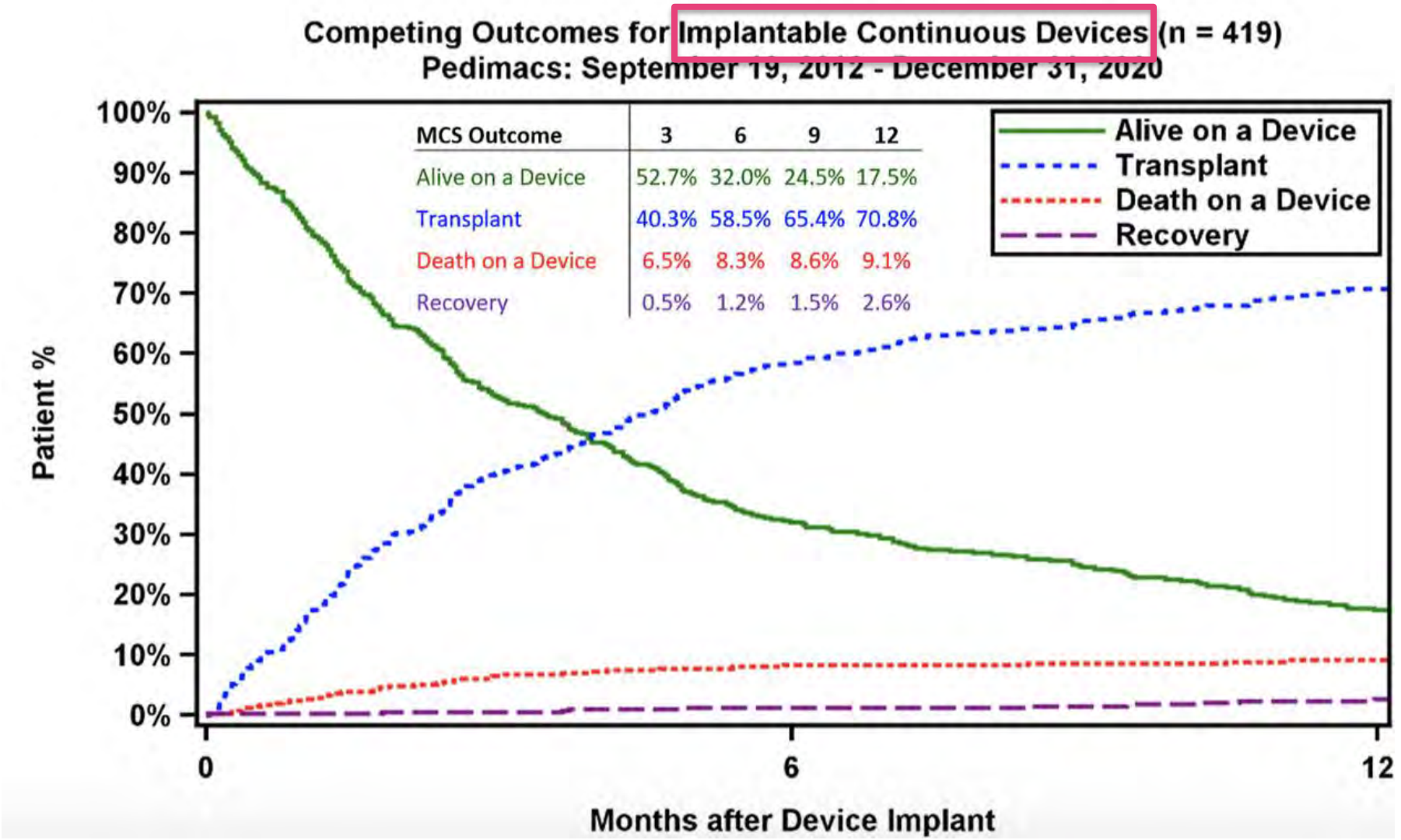

Fifth Annual Pedimacs Report (Rossano & Morales, *et al.* – 2022)

91% of patients achieve a positive outcome

What About Adverse Events?

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*Rate of late complications (≥2 weeks post-implantation)

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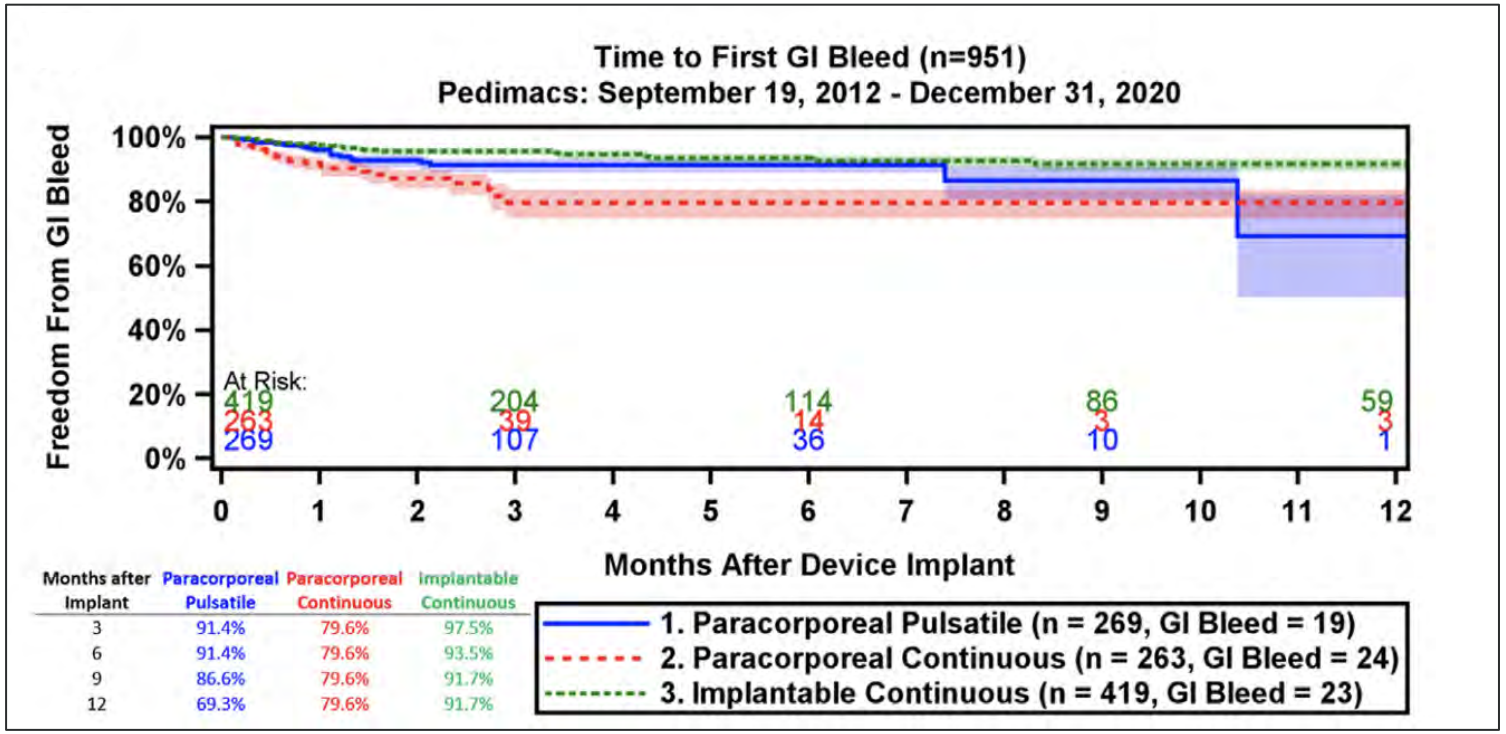

Months after Implant	Paracorporeal Pulsatile	Paracorporeal Continuous	Implantable Continuous
3	91.4%	79.6%	97.5%
6	91.4%	79.6%	93.5%
9	86.6%	79.6%	91.7%
12	69.3%	79.6%	91.7%

SUPERBOWL LVI

Like VAD bridging, we can not will them ALL

What About Adverse Events?

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  - Infection — 28% incidence; 1.2 events/patient-year*

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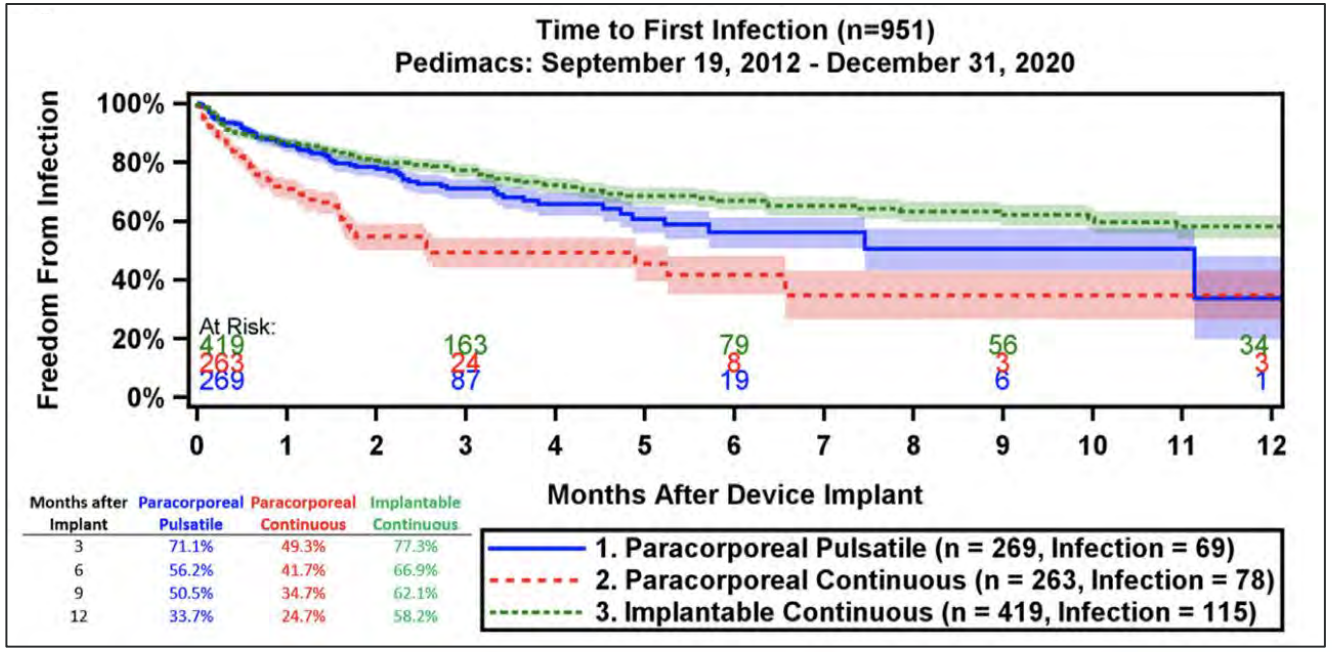

Months after Implant	Paracorporeal Pulsatile	Paracorporeal Continuous	Implantable Continuous
3	71.1%	49.3%	77.3%
6	56.2%	41.7%	66.9%
9	50.5%	34.7%	62.1%
12	33.7%	24.7%	58.2%

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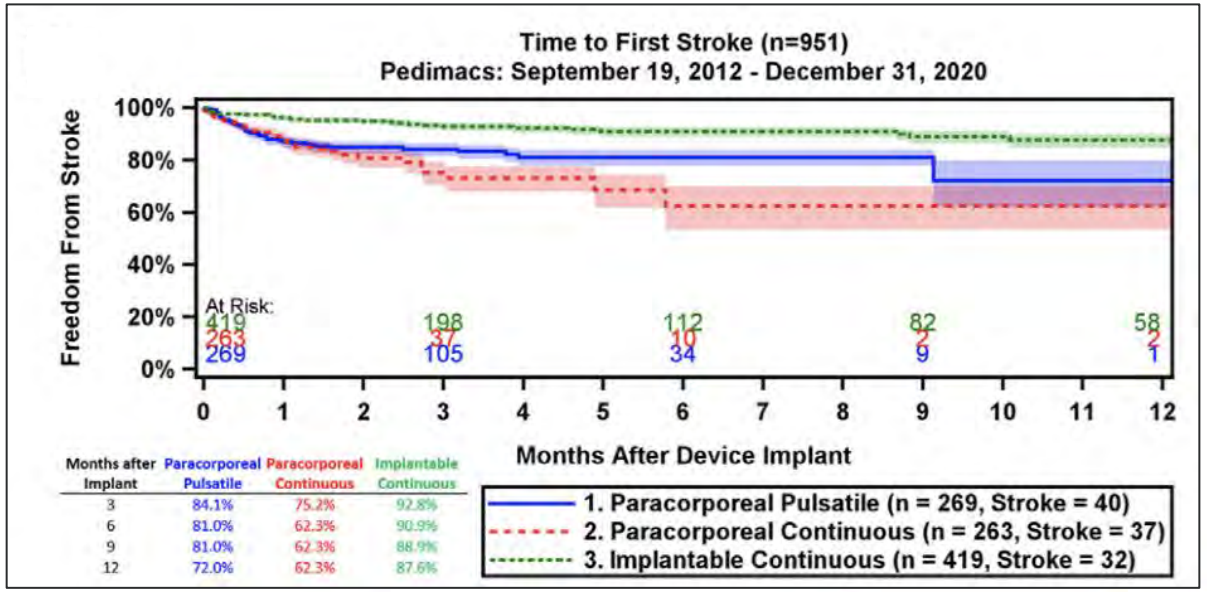

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  - CVA — 11% incidence; 0.2 events/patient-year*
    - Incidence by device type sign. decreased thru ACTION:
      - PP = 15% (ACTION data showing < 11% w/ use of ⬆ BiVal)
      - PC = 14%
      - IC = 8% (ACTION data showing HM3 < 4%)

So in Cincinnati, when do we want to get off the VAD bridge & transplant

At Cincinnati, we like our patients:

- Extubated

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- **Extubated**
- **End-organs recovered**
  - (Normal labs and organ function)

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- End-organs recovered
- Off/minimal sedation

At Cincinnati, we like our patients:

- Extubated
- End-organs recovered
- Off/minimal sedation
- Tolerating enteral feeds

The perils of “limping” to transplant

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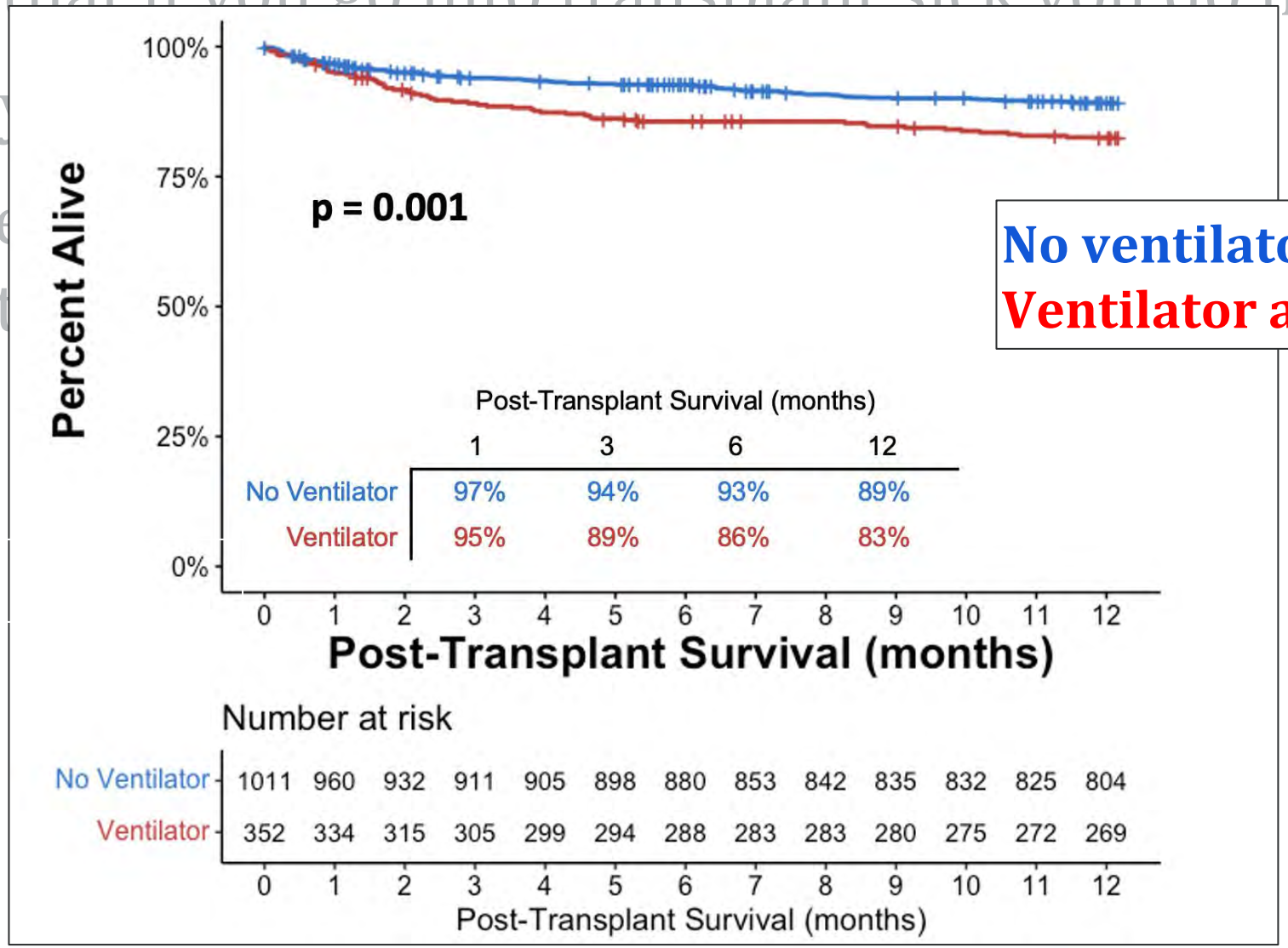
- We know that if you go into transplant sick you will not do well
- Also, many of these risk factors are modifiable
- These modifiable risk factors individually portend inferior post-transplant outcomes

The perils of “limping” to transplant

- We know that if you go into transplant sick you do not do as well
- Also, many
- Modifiable
  transplant

(*Infants*)



No ventilator at transplant
Ventilator at transplant

Greenberg, et al. WJCPHS (In Press)

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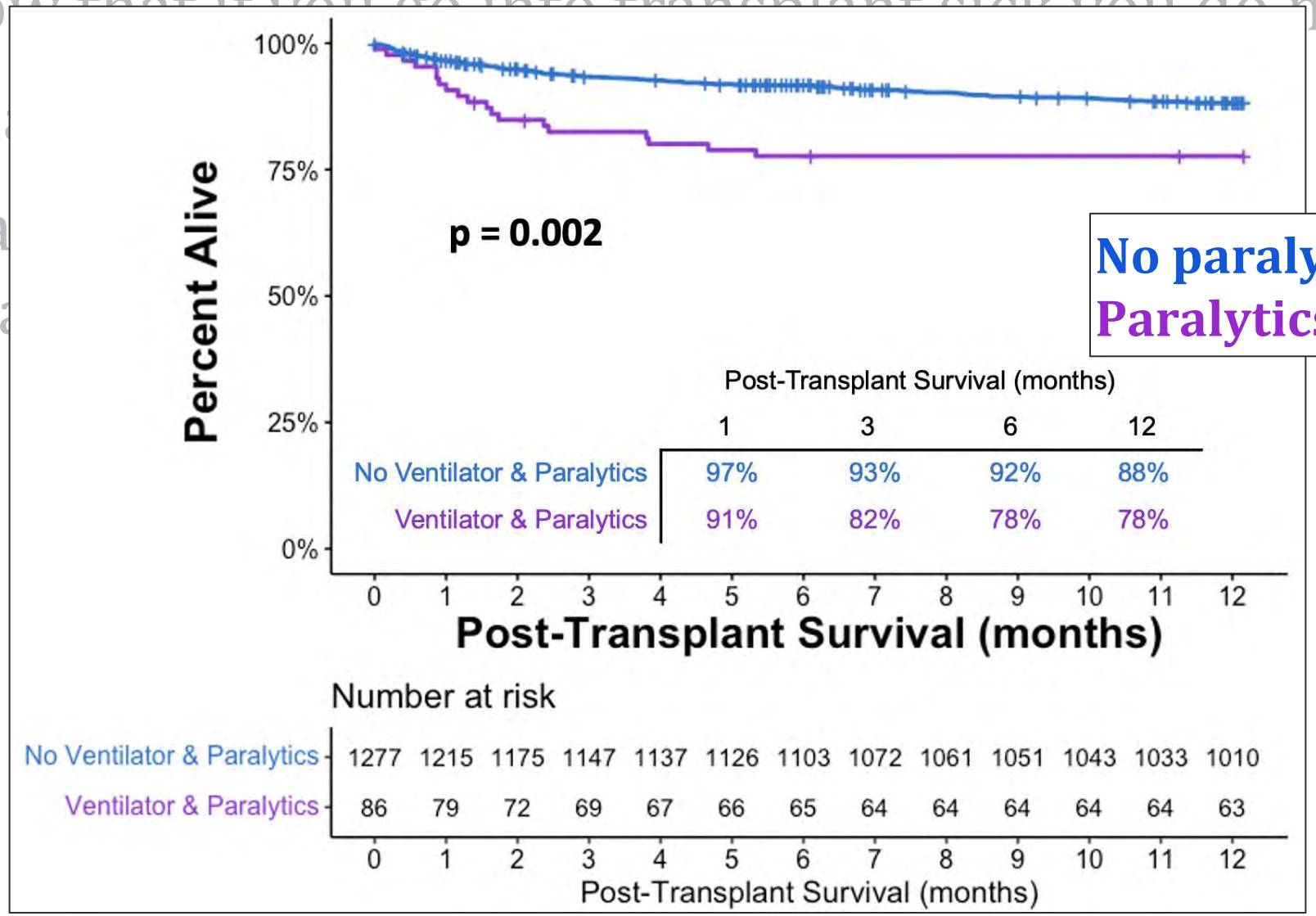

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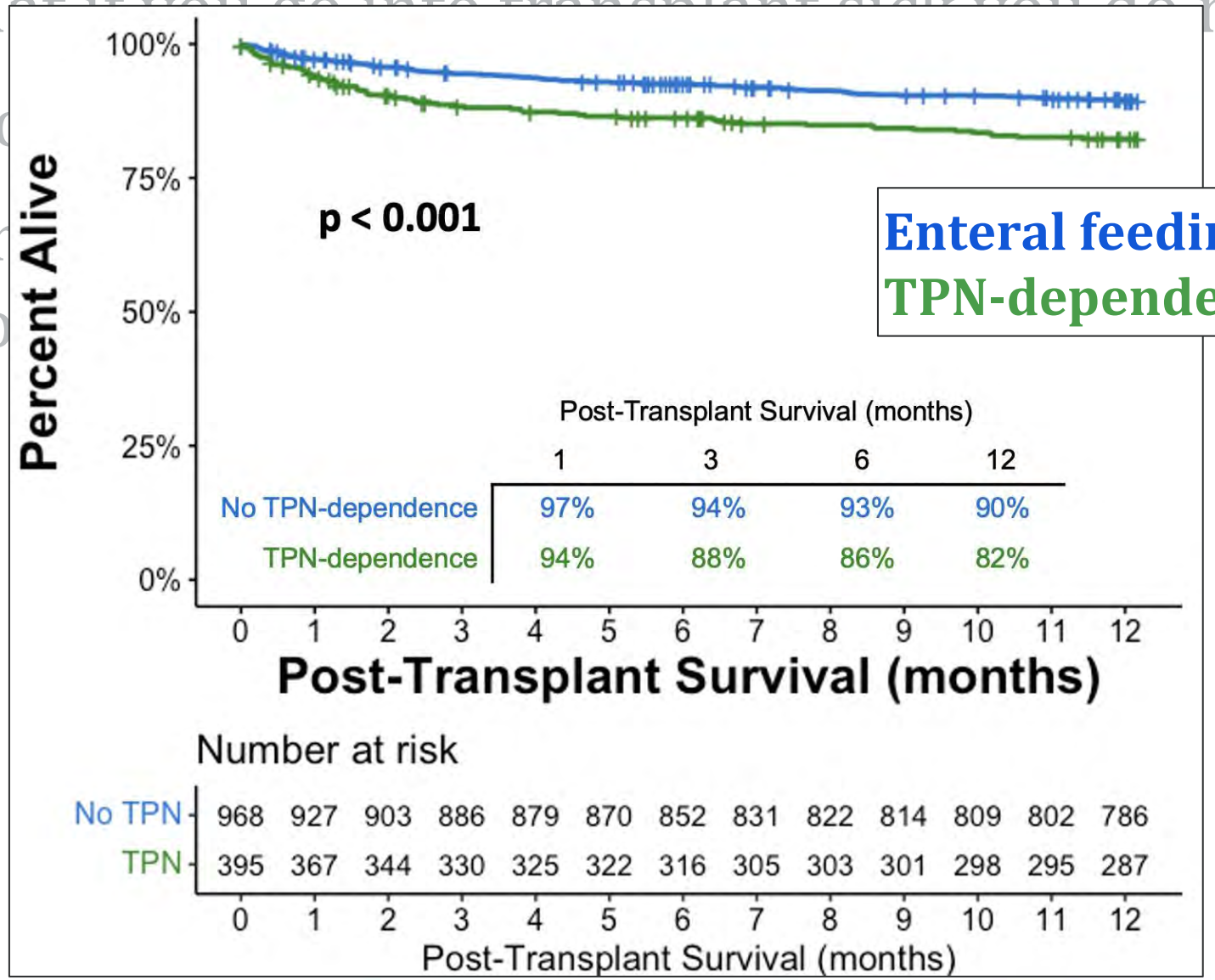

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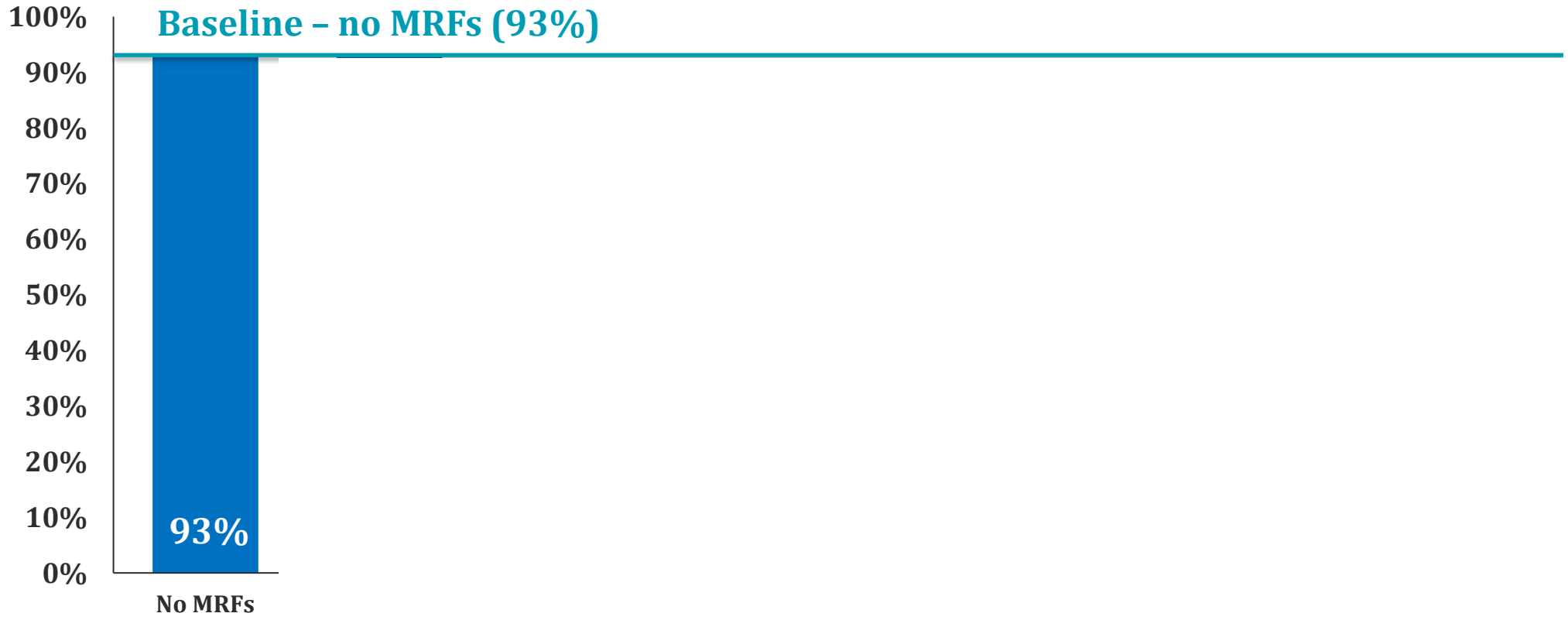

(MRF = modifiable risk factor)

Riggs et al. JTCVS (2020)

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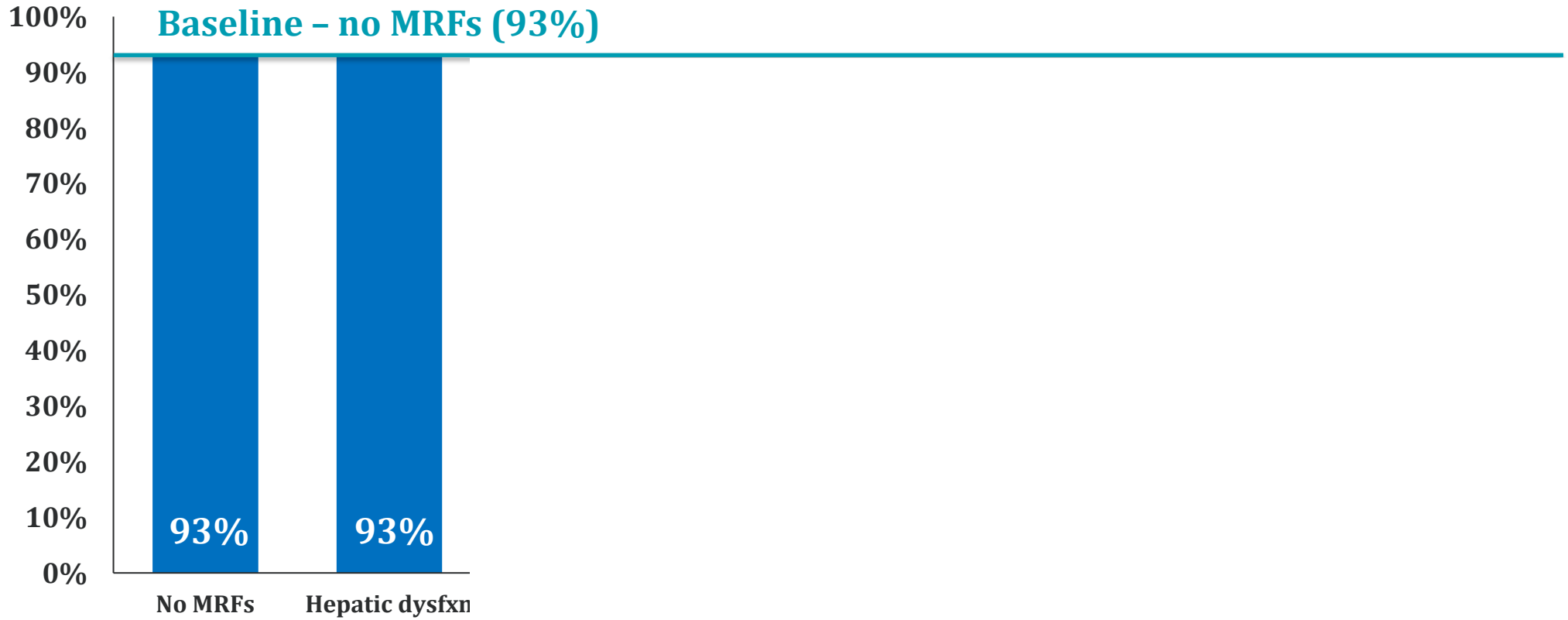

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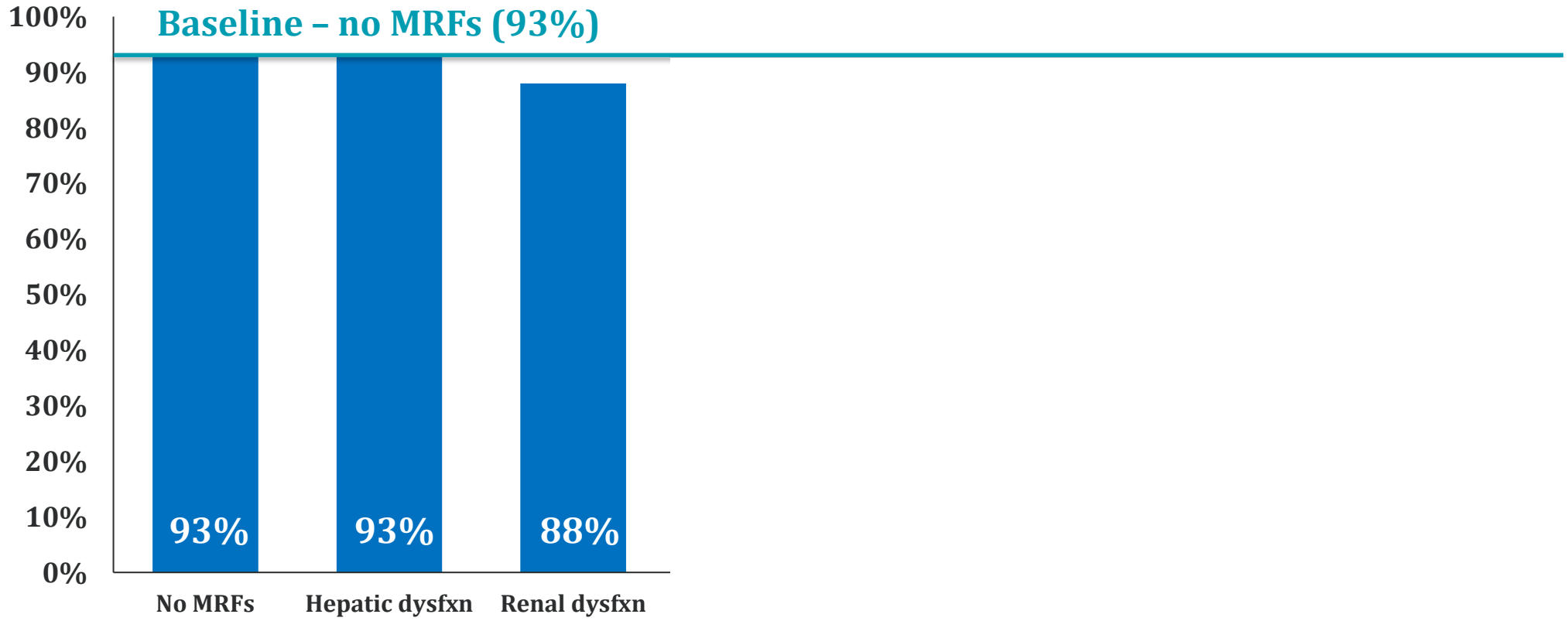

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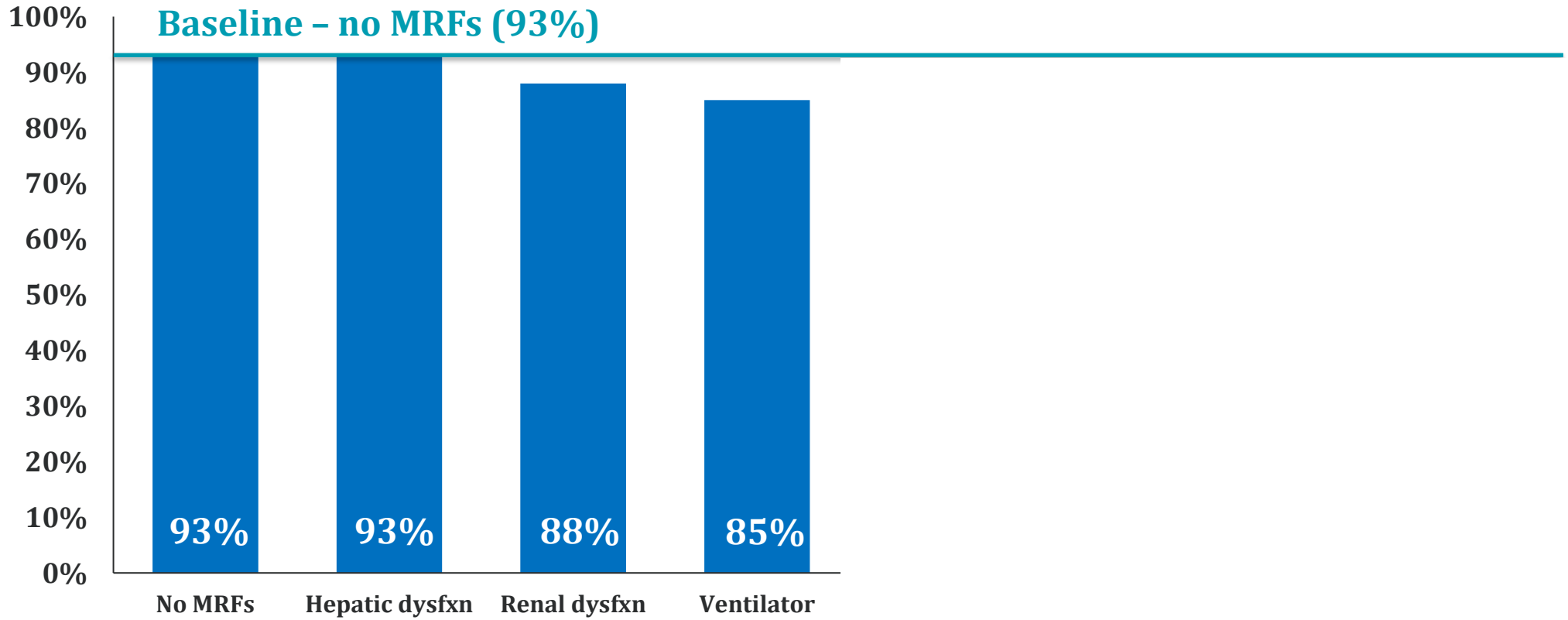

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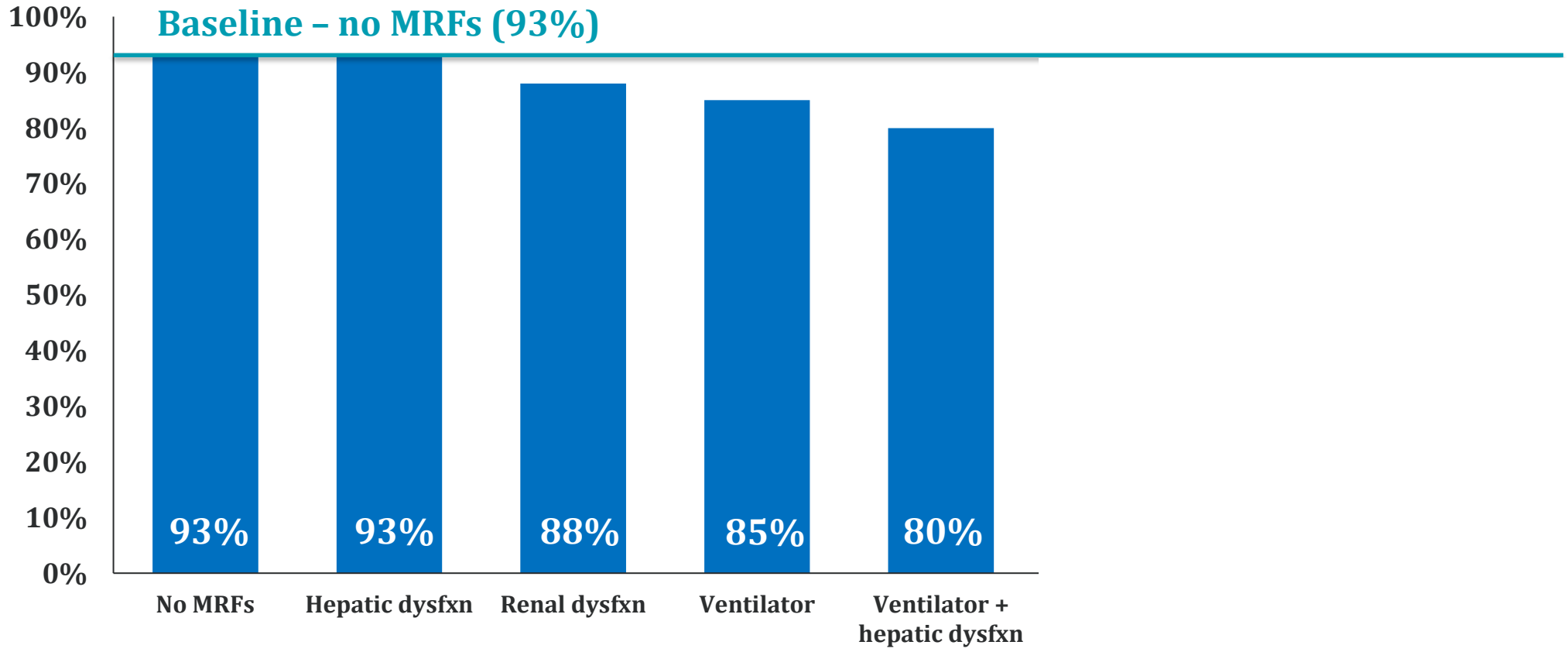

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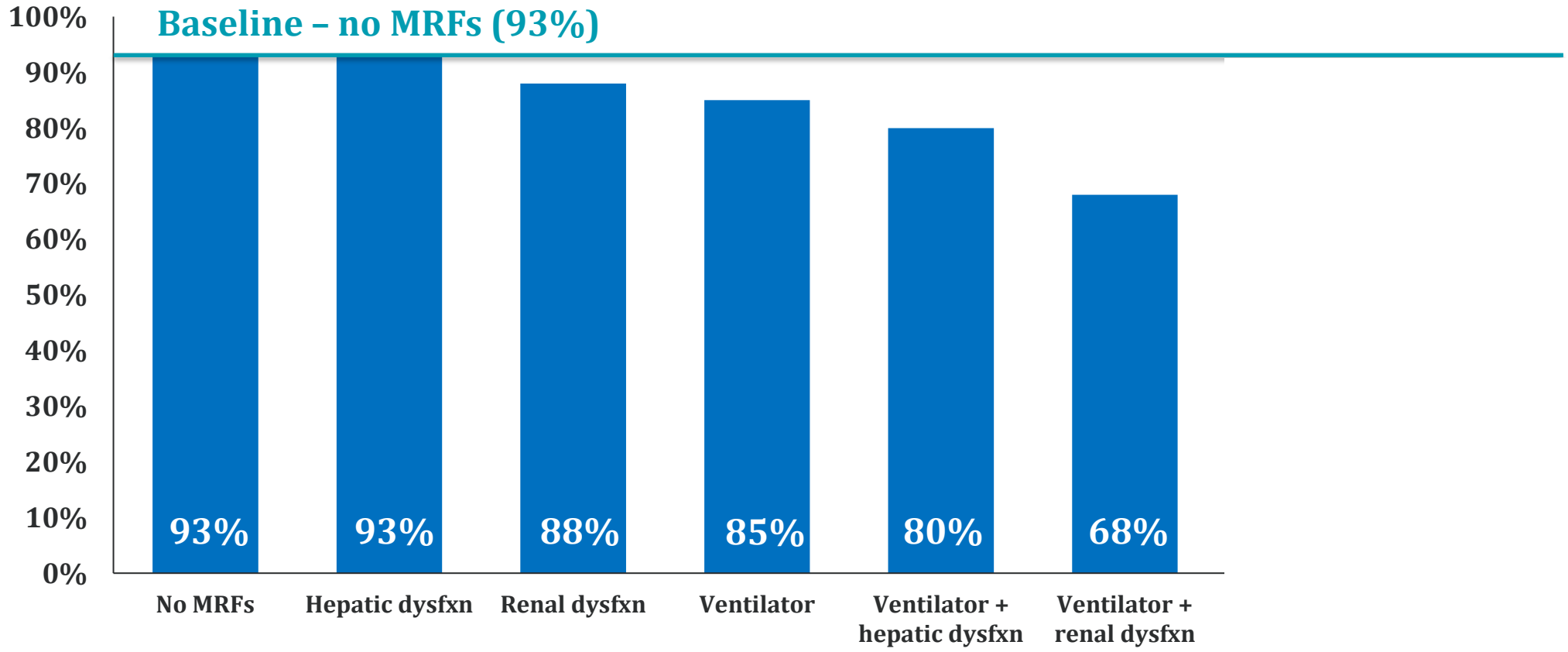

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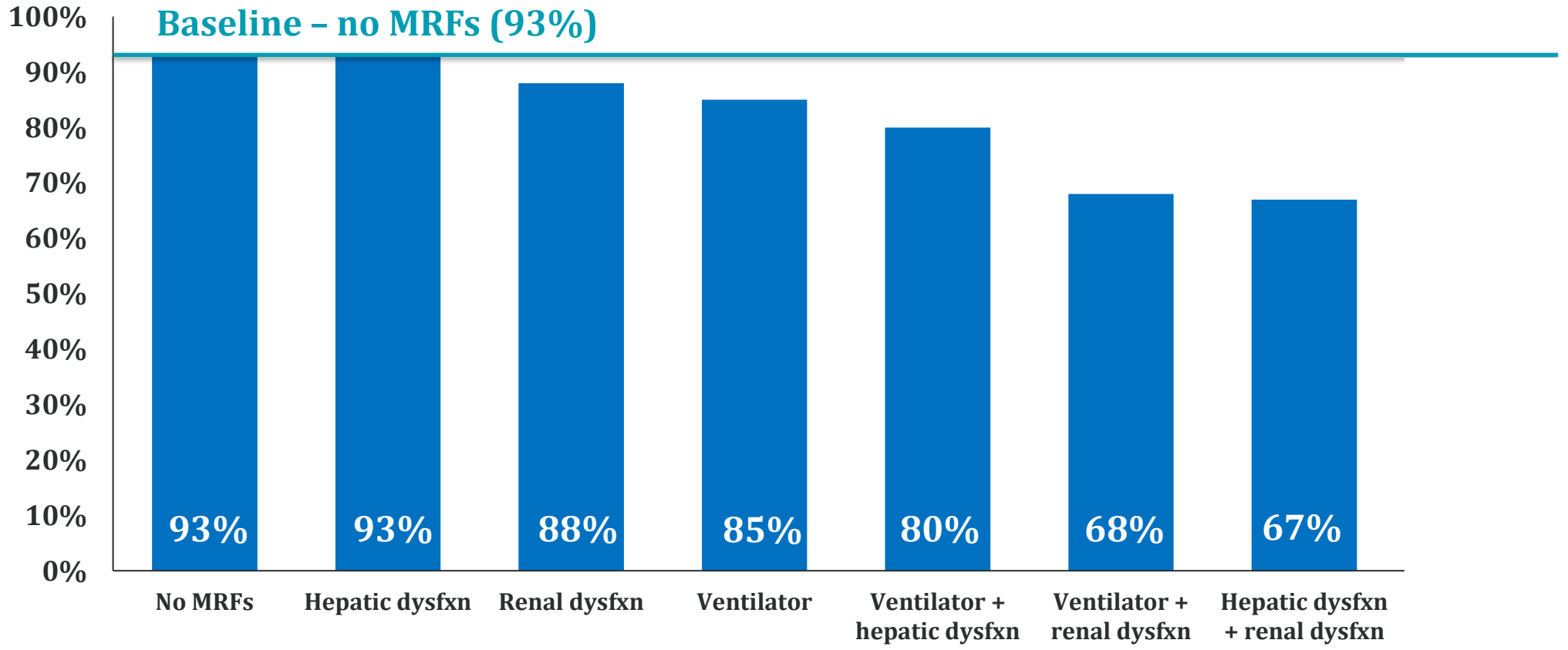

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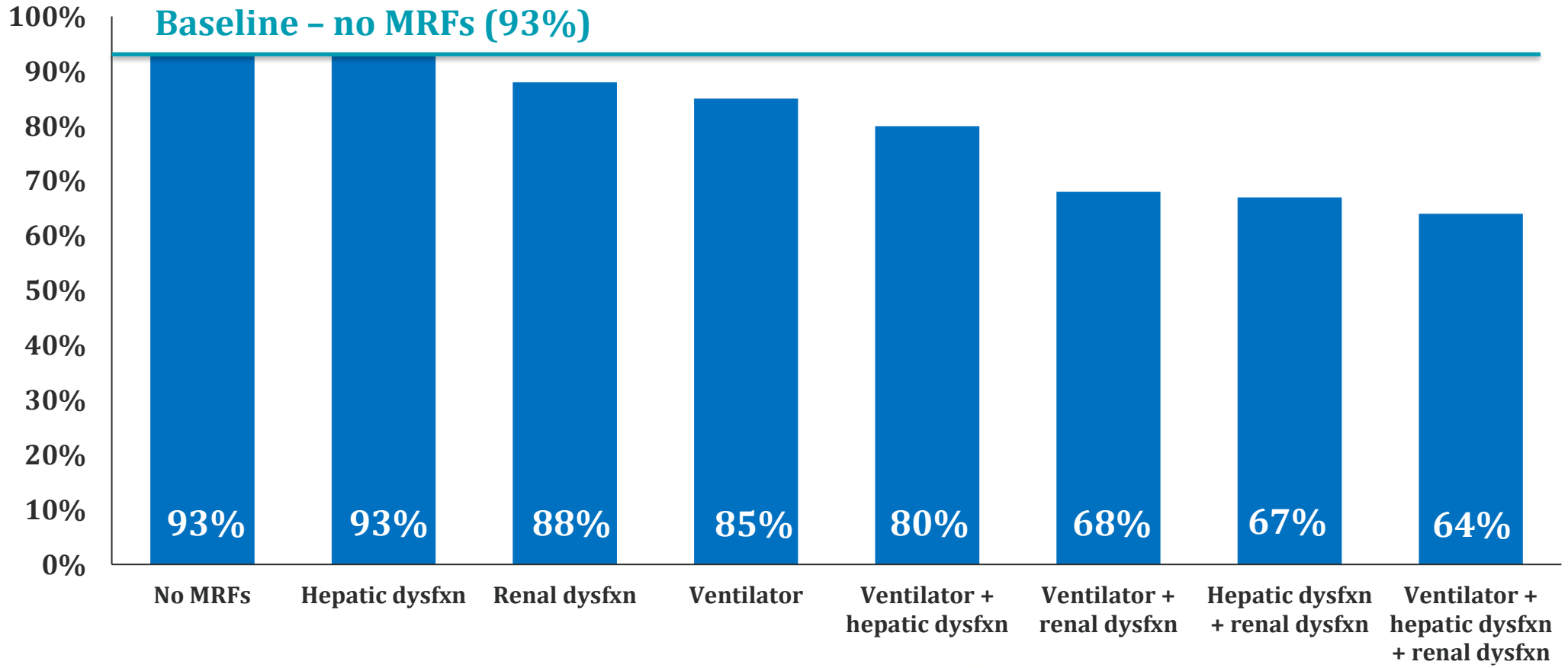

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So how can VAD Help?

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- Clearly, the fewer modifiable risk factors the patient has, the better they do after transplant

The benefits of VAD

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(Thangappan K, et al. ASIAO Journal [2022])

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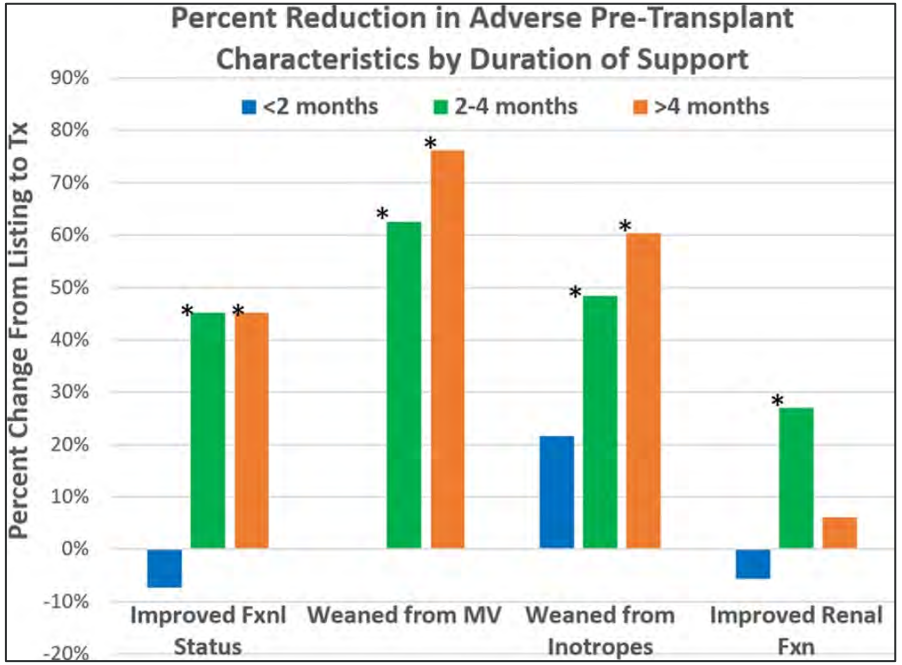
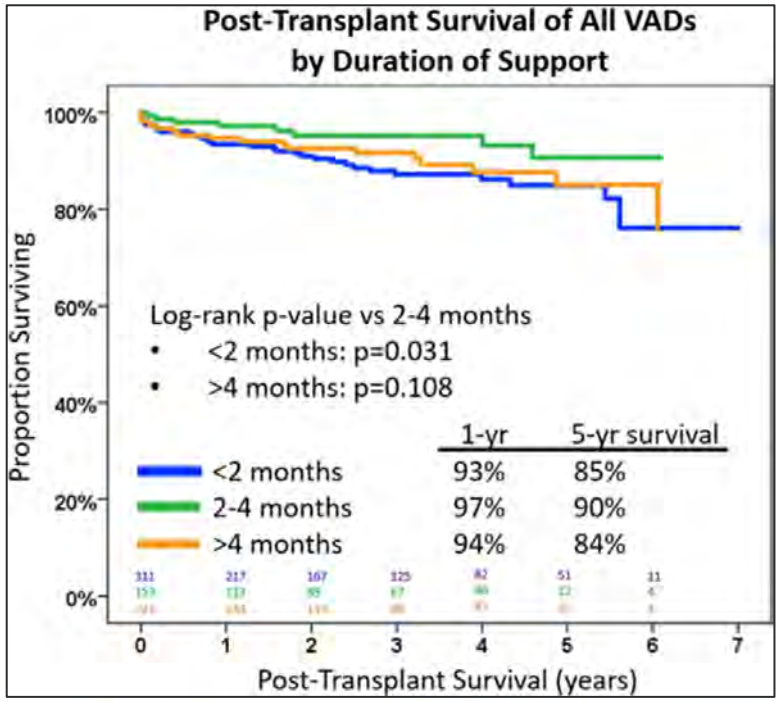
    - ➢ Inotrope requirements decreased **p < 0.001**
    - ➢ Ventilator dependence decreased **p < 0.001**

(Thangappan K, et al. ASIAO Journal [2022])

VAD benefit takes time…

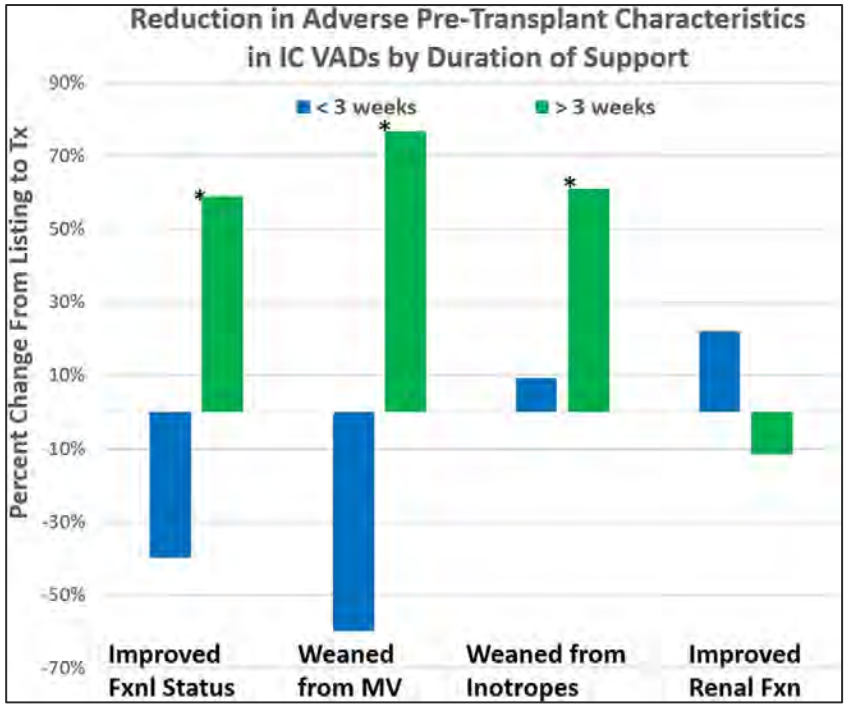
- Renal and hepatic dysfunction improve if given sufficient time on VAD support
  - 2-4 months with PP VADs

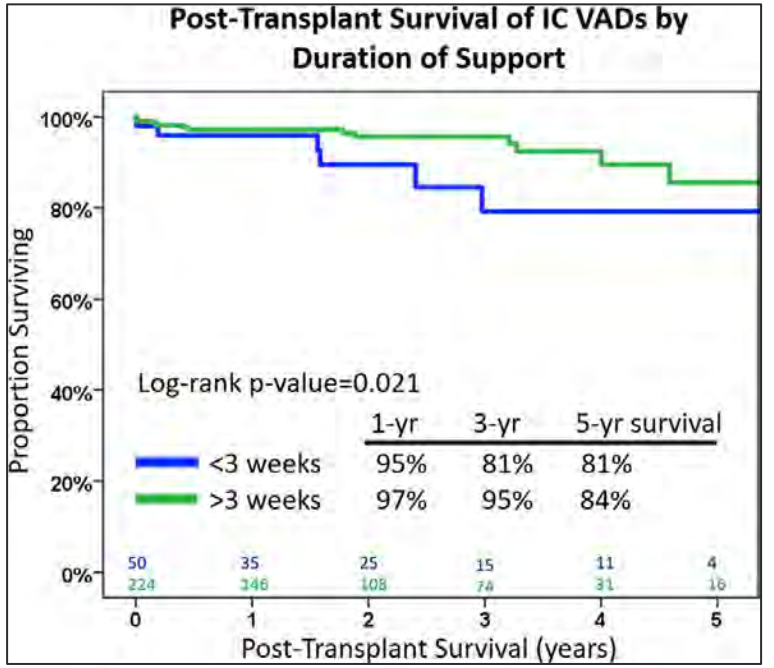




Timing Matters…

- Renal and hepatic dysfunction improve if given sufficient time on VAD support
  - 2-4 months with PP VADs
  - ~3 weeks with IC VADs





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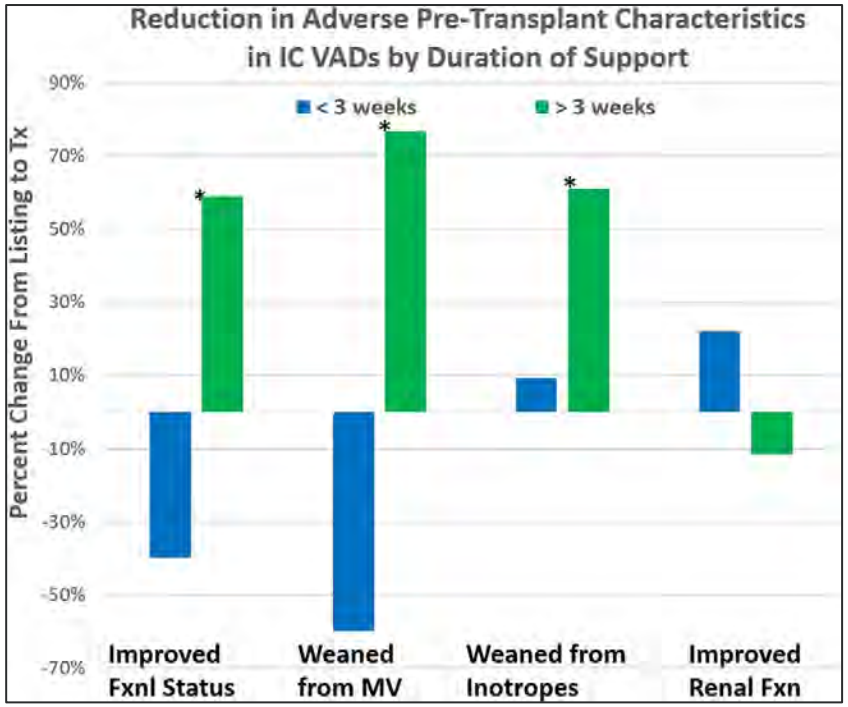
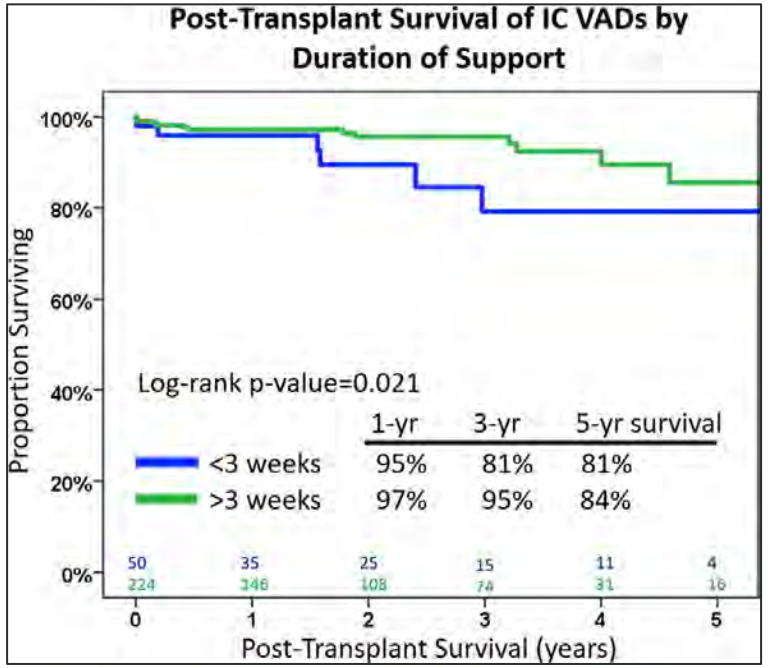
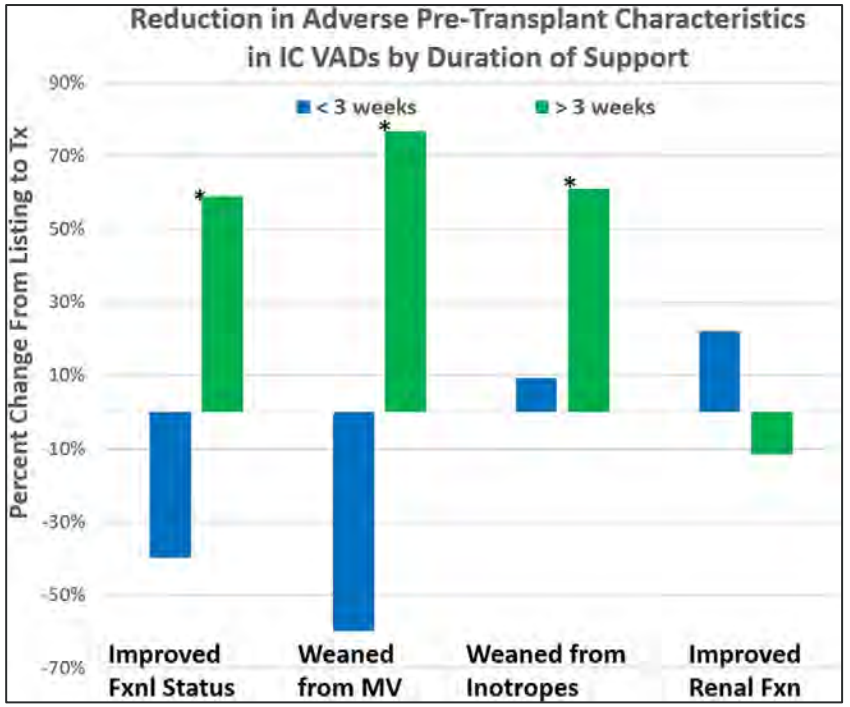
- Same is true for Mechanical ventilation

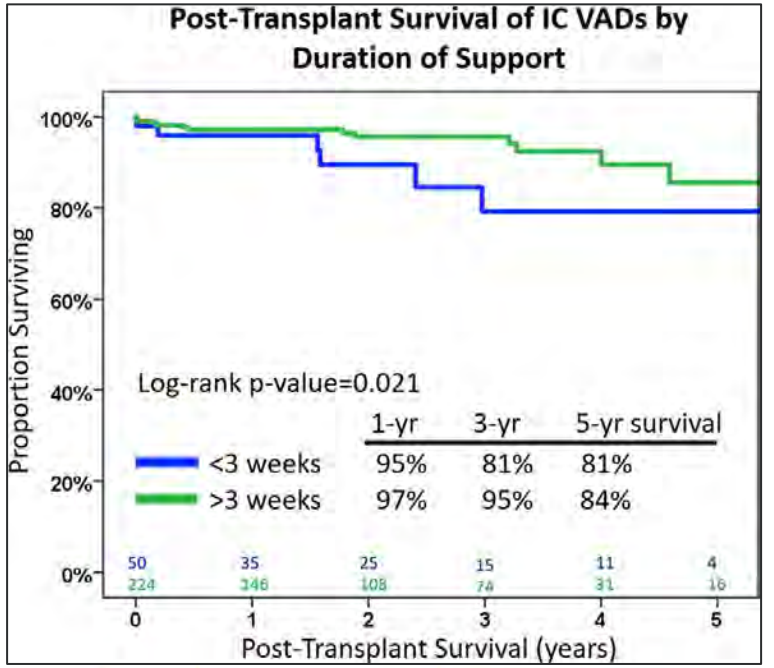




Timing Matters…

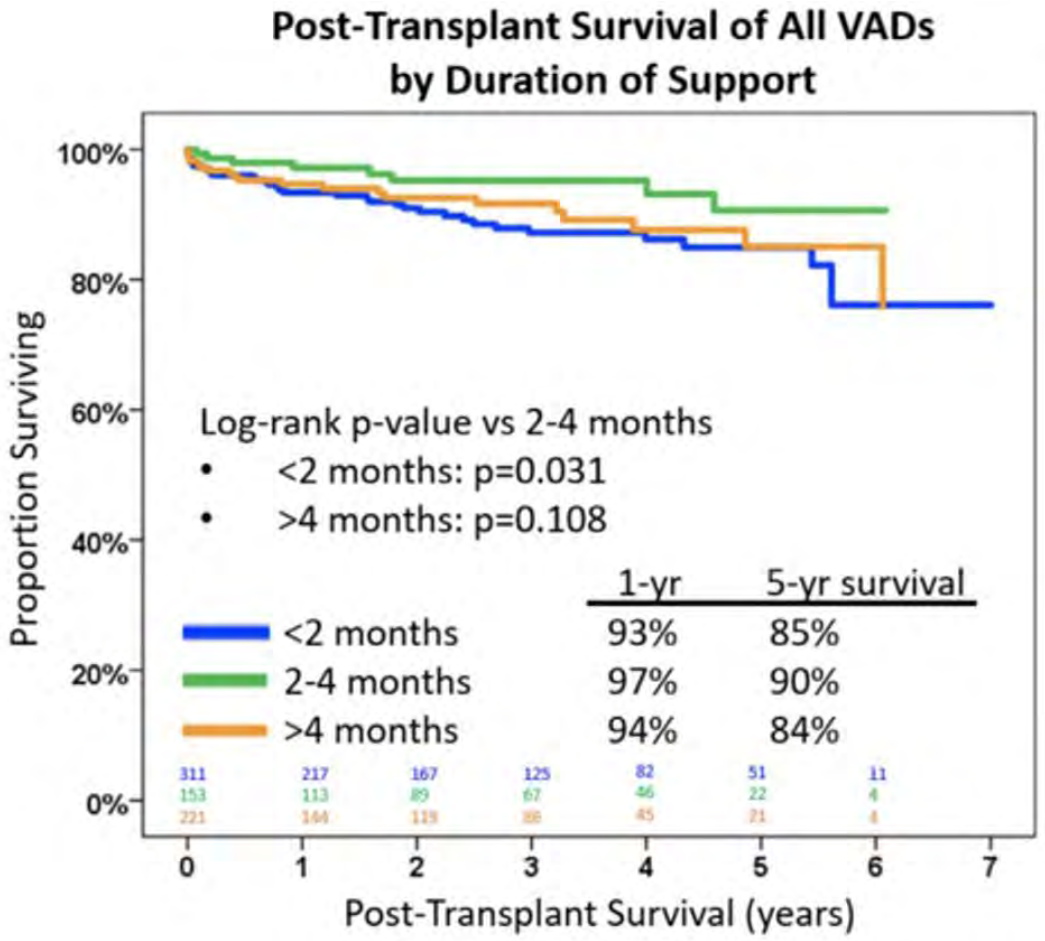
- Renal and hepatic dysfunction improve with sufficient duration of VAD support
    - 2-4 months with PP VADs
    - ~3 weeks with IC VADs
- Same is true for Mechanical ventilation… generally after ~3 weeks





The benefits of VAD

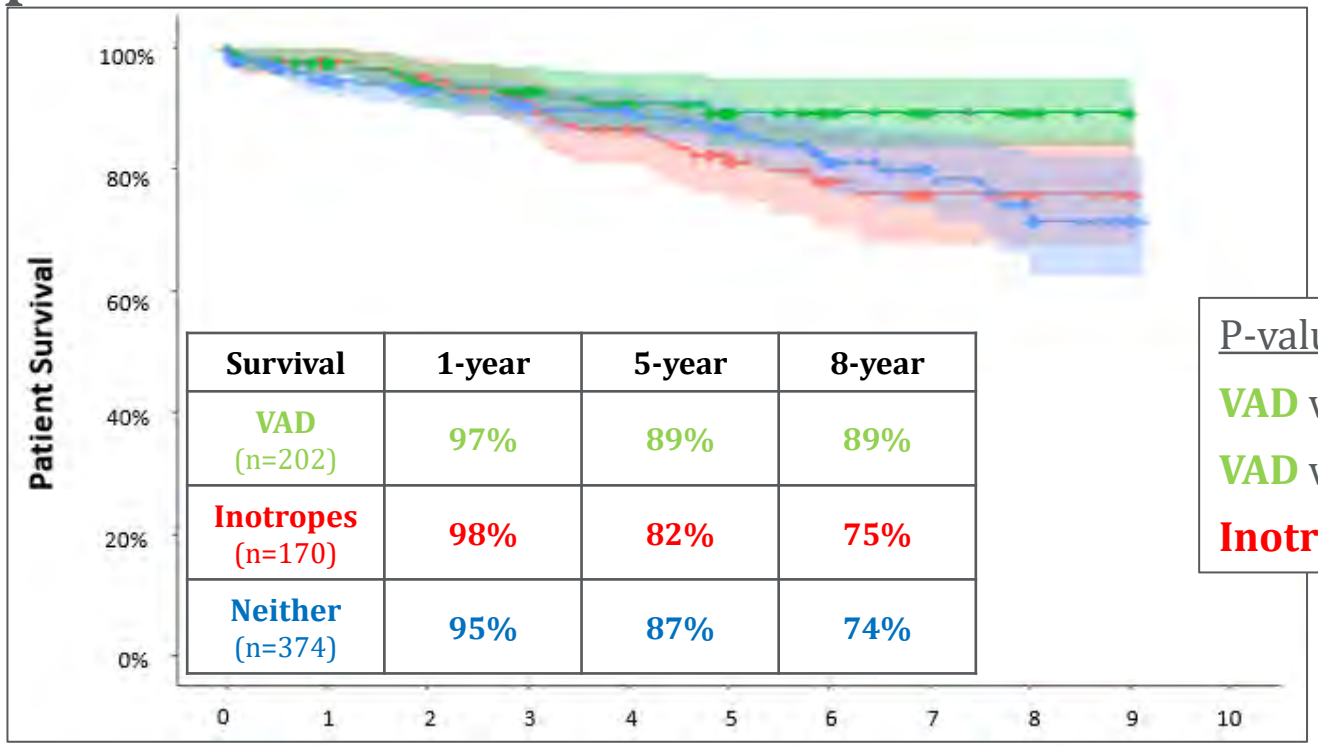
- Timing matters…
- Post-transplant survival also increases with longer VAD BTT (?2-4mo)



Riggs, et al. JTCVS (2020)

The benefits of VAD

- Timing matters…
- Post-transplant survival also increases with longer VAD BTT
- In the current era, outpt VAD BTT has same early post-tx survival as outpt inotropes



Survival	1-year	5-year	8-year
VAD (n=202)	97%	89%	89%
Inotropes (n=170)	98%	82%	75%
Neither (n=374)	95%	87%	74%

P-values:

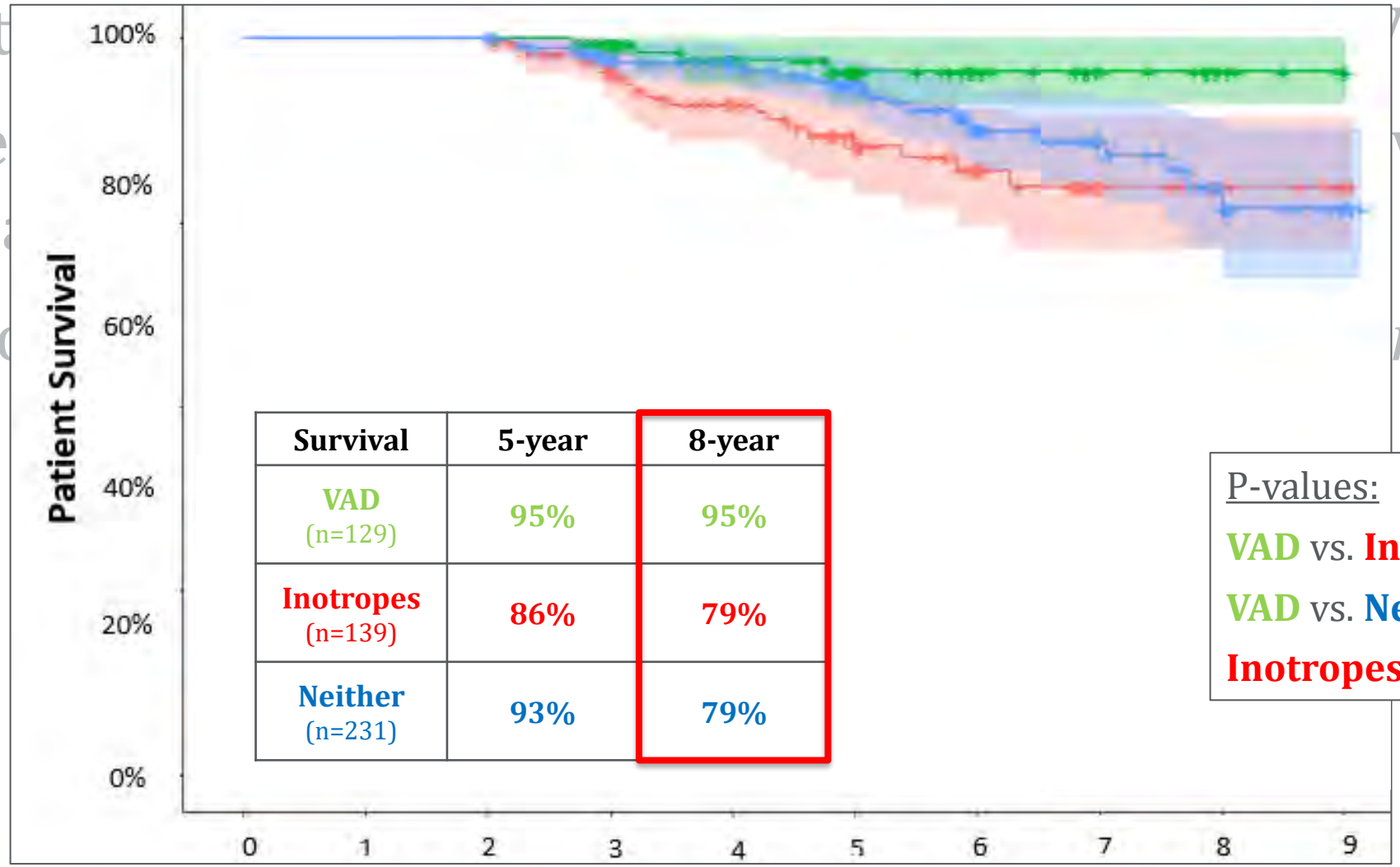
VAD vs. Inotropes	0.098
VAD vs. Neither	0.103
Inotropes vs. Neither	0.743

The benefits of VAD

- Timing matters…
- Post-transplant survival also increases with longer VAD BTT
- In the current era, outpt VAD BTT has same early post-tx survival as outpt inotropes
- However, at 2yr conditional post-tx survival, outpt VAD BTT *outperforms* outpt inotropes or outpts supported with neither

The benefits of VAD

- Timing matters…
- Post-t… …AD BTT
- In the… …vival comp…
- At two… …*ms* inotropes



Survival	5-year	8-year
VAD (n=129)	95%	95%
Inotropes (n=139)	86%	79%
Neither (n=231)	93%	79%

P-values:

VAD vs. Inotropes	**0.006**
VAD vs. Neither	0.053
Inotropes vs. Neither	0.206

The benefits of VAD

- The bottom line:

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  - Aggressive pre-transplant risk factor modification should be pursued when modifiable risk factors are present

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- The bottom line:
  - Aggressive pre-transplant risk factor modification should be pursued when modifiable risk factors are present
  - VADs can help!
  - At our institution, we advocate heavily for making patients status 7 or not listing them until they are optimized on their VAD & *ready for transplantation*

Main take-aways:

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- Who should be considered for a VAD bridge?

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  - All children awaiting transplantation with modifiable risk factors

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  - When they're ready! *(Physiologically optimized)*

Main take-aways:

- **Who should be considered for a VAD bridge?**
  - All children awaiting transplantation with modifiable risk factors

- **When should we exit the VAD bridge & transplant?**
  - When they're ready! *(Physiologically optimized)*
    - Normal end-organ function, optimal nutritional status, optimal functional status

REMEMBER…….

OUR GOAL IS NOT TO JUST GET OUR PATIENTS TO TRANSPLANT BUT TO GET THEM THERE IN A STATE WHERE THEY CAN DO WELL AFTER TRANSPLANT & LIVE A LONG & HEALTHY POST-TX LIFE

Cincinnati Children's
changing the outcome together

Questions?

Cincinnati Children's
changing the outcome together

Thank You

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Special Considerations

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    - VADs are comparatively underutilized in CHD

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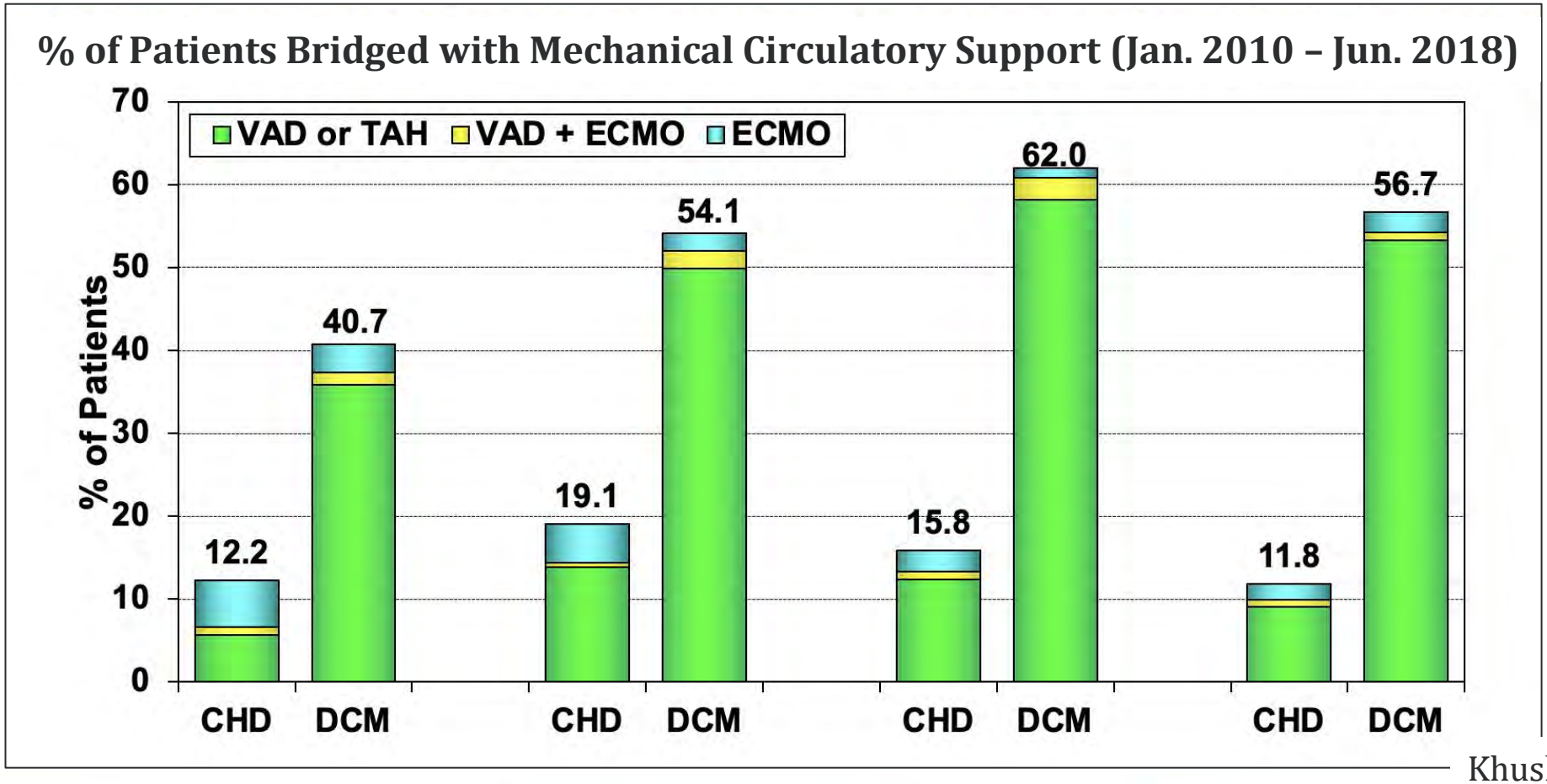

Khush, et al. JHLT (2019)

Special Considerations

- What about CHD patients?
  - VADs are comparatively underutilized in CHD
  - With optimal patient selection and an experienced team, CHD patients (including those with single-ventricle physiology) can achieve optimal outcomes

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Special Considerations

- What about CHD patients?
  - VADs are comparatively underutilized in CHD
  - With optimal patient selection and an experienced team, CHD patients (including those with single-ventricle physiology) can achieve optimal outcomes

- How about infants and smaller children?
  - VAD devices are limited in children (Berlin Heart EXCOR is the best available device currently)…

Special Considerations

- What about CHD patients?
  - VADs are comparatively underutilized in CHD
  - With optimal patient selection and an experienced team, CHD patients (including those with single-ventricle physiology) can achieve optimal outcomes

- How about infants and smaller children?
  - VAD devices are limited in children (Berlin Heart EXCOR is the best available device currently)… but smaller children derive the same benefits from VAD as larger children

Special Considerations

- What about CHD patients?
  - VADs are comparatively underutilized in CHD
  - With optimal patient selection and an experienced team, CHD patients (including those with single-ventricle physiology) can achieve optimal outcomes

- How about infants and smaller children?
  - In an analysis of >1800 Berlin EXCOR BTT, significant improvement in survival existed for children <10 kg in the recent era (post-2012)…

Miera & Morales, et al. EJCTS (2019)

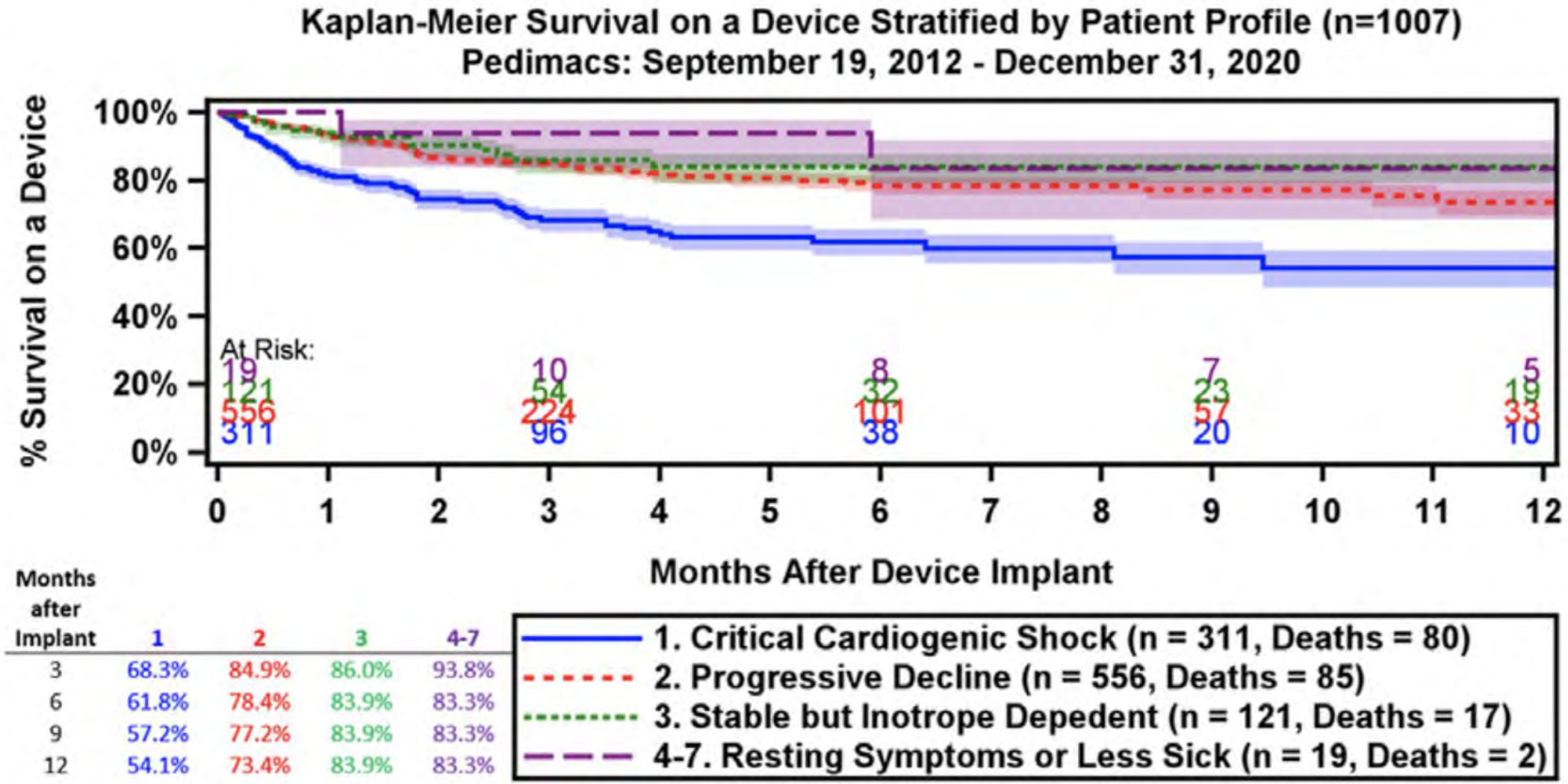
Special Considerations

- What about CHD patients?
  - VADs are comparatively underutilized in CHD
  - With optimal patient selection and an experienced team, CHD patients (including those with single-ventricle physiology) can achieve optimal outcomes

- How about infants and smaller children?
  - In an analysis of >2,000 Berlin EXCOR BTT, significant improvement in survival existed for children <10 kg in the recent era (post-2012)… and survival was similar between children 5-10 kg & >10 kg

Miera & Morales, et al. EJCTS (2019)

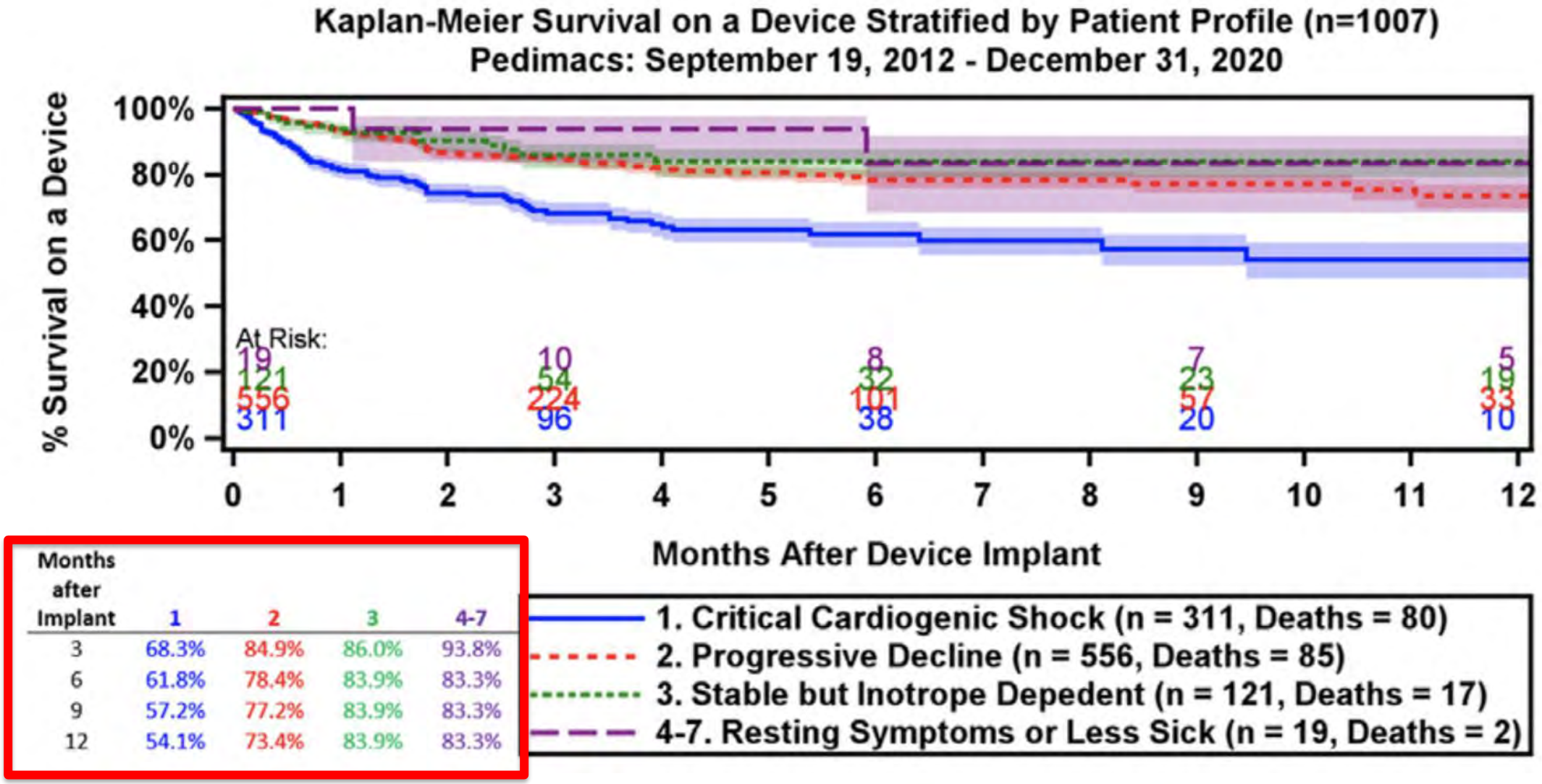
Like Transplant



Months after Implant	1	2	3	4-7
3	68.3%	84.9%	86.0%	93.8%
6	61.8%	78.4%	83.9%	83.3%
9	57.2%	77.2%	83.9%	83.3%
12	54.1%	73.4%	83.9%	83.3%

Fifth Annual Pedimacs Report (Rossano & Morales, *et al.* – 2022)

Current Landscape of VAD Therapy



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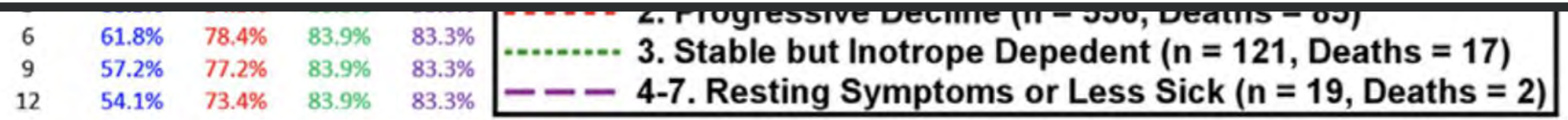
Current Landscape of VAD Therapy

Kaplan-Meier Survival on a Device Stratified by Patient Profile (n=1007)
Pedimacs: September 19, 2012 - December 31, 2020

Months after implant	Critical cardiogenic shock	Progressive decline	Stable but inotrope-dependent	Resting symptoms
3	68%	85%	86%	94%
6	62%	78%	84%	83%
9	57%	77%	84%	83%
12	54%	73%	84%	83%



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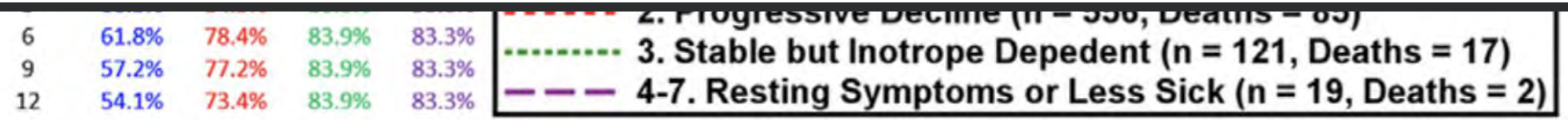

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Disclosures

• Abbott Medical, Inc.	*Consultant*		
• Azyio, Inc.	*Consultant*		
• Berlin Heart, Inc.	*Consultant*	*Medical Advisory Board*	
• CorMatrix, Inc.	*Consultant*	*Medical Advisory Board*	
• Syncardia, Inc.	*Consultant*	*Instructor*	*Proctor*
• Xeltis, Inc.	*Consultant*		