

# Society of Thoracic Surgeons

Intermacs & Pedimacs User Group  
Webinar

August 30, 2023



**STS National Database™**  
Trusted. Transformed. Real-Time.

# User Group Webinar

- Welcome and Introductions
- STS Updates
- AQO 2023
- Dr. Kiernan
- User Feedback



# AGENDA



# The Intermacs Data Warehouse Team

Rama Rudraraju, PhD, Director of Programming, Intermacs Data Warehouse

Maceo Cleggett , Clinical Data Analyst , Intermacs Data Warehouse

Jeanne Anne Love, Patient Management Director, Intermacs Data Warehouse

John Pennington, MSHI, Senior Data Manager, Intermacs Data Warehouse

Chase Lenderman, Application Developer, Intermacs Data Warehouse



# Contact Information

Kathryn Hollifield, BSN, RN STS National Database Manager, Intermacs and Pedimacs

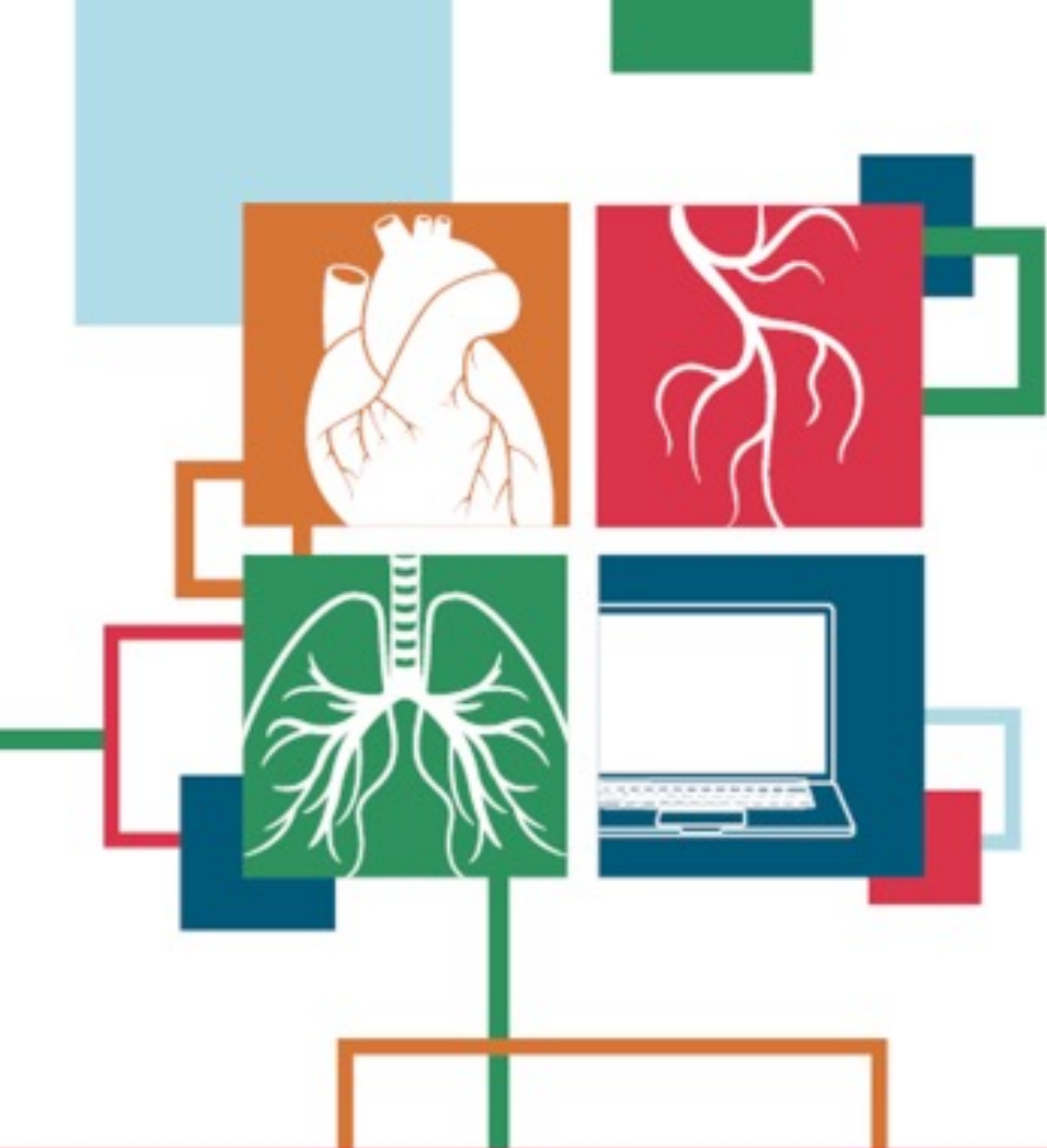
- [khollifield@sts.org](mailto:khollifield@sts.org)

Patricia Potter, BSN, RN, Intermacs Data warehouse Manager of Clinical Affairs

- [patricia.potter@kirso.net](mailto:patricia.potter@kirso.net)

Database Operational Questions

- [intermacsfaq@sts.org](mailto:intermacsfaq@sts.org)



# ADVANCES IN QUALITY & OUTCOMES: A Data Managers Meeting

SEPTEMBER 26-29, 2023 ■ VIRTUAL



**STS National Database™**

Trusted. Transformed. Real-Time.



# ADVANCES IN QUALITY & OUTCOMES: A Data Managers Meeting

SEPTEMBER 26-29, 2023 ■ VIRTUAL

Education

News ▾

Resources ▾

Education

Events

Online Learning

Annual Meeting

Thoracic Surgical  
Curriculum

Calendar of Events

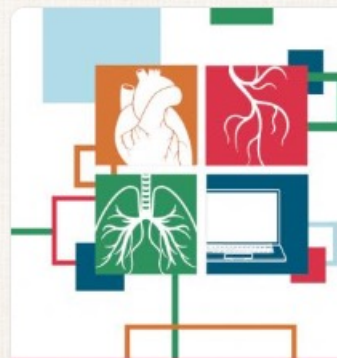
Educational Collaborations

Webinars

E-Book

TSF Awards & Fellowships

Scholarships



## ADVANCES IN QUALITY & OUTCOMES: A Data Managers Meeting

SEPTEMBER 26-29, 2023 ■ VIRTUAL



STS National Database™  
Trusted. Transformed. Real-Time.

📅 Event

### 2023 Advances in Quality & Outcomes: A Data Managers Meeting

Discussions on valuable research and important clinical findings with the goal of improving data collection and patient outcomes.

📅 Sep 26—29, 2023

📍 Virtual



STS National Database™  
Trusted. Transformed. Real-Time.





## AQO Registration Is Open!

### Pricing

Registration Type	Price
One Day: STS Member	\$200
One Day: Non-Member	\$250
Multi-day: STS Member	\$300
Multi-day: Non-Member	\$400
Multi-day: STS Industry/vendor	\$500



# Upcoming Intermacs Webinars

## Intermacs User Group Webinar

- October 25<sup>th</sup> @ 1 pm CT





# Intermacs Database

---

## Intermacs Webinars

### Intermacs User Group Call

August 30 at 2 p.m. ET • 1 p.m. CT

Call In: 888-475-4499 or 877-853-5257 or 312-626-6799

Meeting ID: 557 707 151

[International Dial-in Numbers](#)

[Join Webinar](#)

### Most Recent Intermacs Webinar

[View Webinar Recording](#)

[View Slides](#) - Intermacs/Pedimacs Quality Assurance Report Overview Quarterly Webinar - April 20, 2023

[View Past Intermacs Webinars](#)



# PreImplant form

---

**ECMO: Present at the time of durable MCS  
device implant**

- ☐ Yes  
☐ No  
☐ Unknown

---

**Total Number of days on ECMO**

ST: ☐ Unknown

---



# Implant form

**Concomitant surgery**  
Planned or accompanying LVAD procedure

- ☐ None
- ☐ ASD closure
- ☐ PFO closure
- ☐ CABG
- ☐ VSD closure
- ☐ Congenital cardiac surgery, other
- ☐ Aortic Valve Procedure
- ☐ Aortic Valve Surgery - Replacement - Biological
- ☐ Aortic Valve Surgery - Replacement - Mechanical
- ☐ Mitral Valve Surgery - Repair
- ☐ Mitral Valve Surgery - Replacement - Biological
- ☐ Mitral Valve Surgery - Replacement - Mechanical
- ☐ Tricuspid Valve Surgery - Repair - DeVega
- ☐ Tricuspid Valve Surgery - Repair - Ring
- ☐ Tricuspid Valve Surgery - Repair - Other
- ☐ Tricuspid Valve Surgery - Replacement - Biological
- ☐ Tricuspid Valve Surgery - Replacement - Mechanical
- ☐ Tricuspid Valve Surgery - Excision
- ☐ Pulmonary Valve Surgery - Repair
- ☐ Pulmonary Valve Surgery - Replacement - Biological
- ☐ Pulmonary Valve Surgery - Replacement - Mechanical
- ☐ Left ventricular aneurysmectomy
- ☐ Other, specify
- ☐ Arrhythmia surgery (ablation)
- ☐ Ligation of left atrial appendage
- ☐ Temporary MCS Removal (ECMO, IABP removal documented here)

☒ Extracorporeal Membrane Oxygenation (ECMO Insertion)

Total Number of days the patient was on  
ECMO

ST: ☐ Unknown



# Explant form

ST= ☐ Unknown

**Was the patient on ECMO at any time  
since implant of their durable LVAD?**

- ☐ Yes  
☐ No  
☐ Unknown

**Total number of days on ECMO**

ST= ☐ Unknown



# Death form

---

**Was the patient on ECMO at any time  
since implant of their durable LVAD?**

- ☐ Yes  
☐ No  
☐ Unknown

---

**Total number of days on ECMO**

ST= ☐ Unknown

---



# Implant Discharge form

**Was ECMO initiated at any time after  
VAD implant?**

- ☐ Yes  
☐ No  
☐ Unknown

**Total Number of days on ECMO?**

ST= ☐ Unknown



# Open Discussion

---



Please use the Q&A  
Function.



We will answer as many  
questions as possible.



We encourage your  
feedback and want to  
hear from you!



# STS National Database™

Trusted. Transformed. Real-Time.

THANK YOU FOR JOINING!



# Kirklin Institute for Research in Surgical Outcomes

## STS-Intermacs & Pedimacs User's Webinar

### Early Acute Right Heart Failure: RVAD use in LVAD Recipients

Michael Kiernan, MD, MS, MBA

Associate Professor of Medicine, TUSM

Associate Chief, Division of Cardiology, Tufts Medical Center

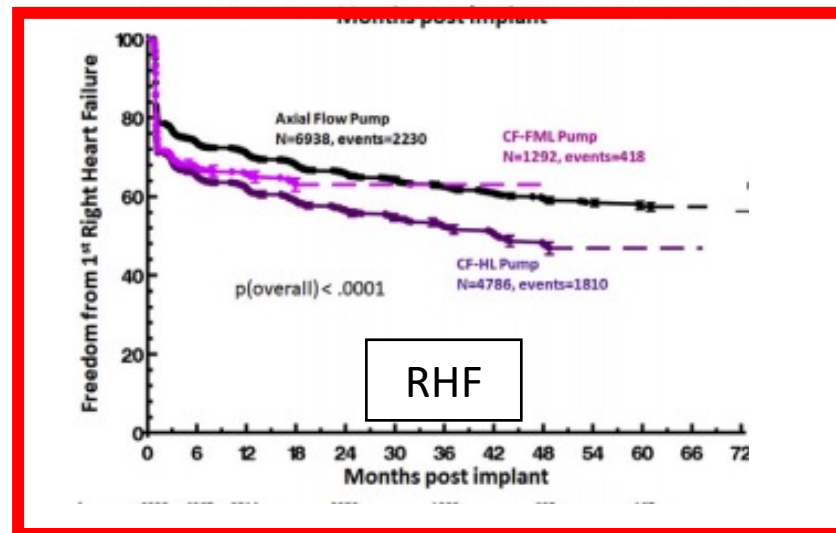
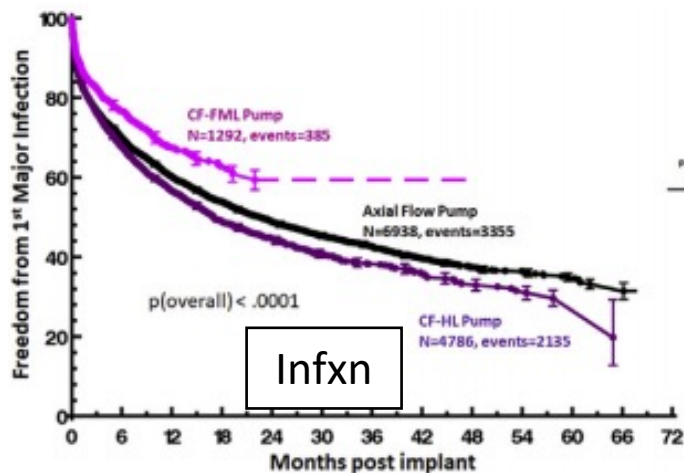
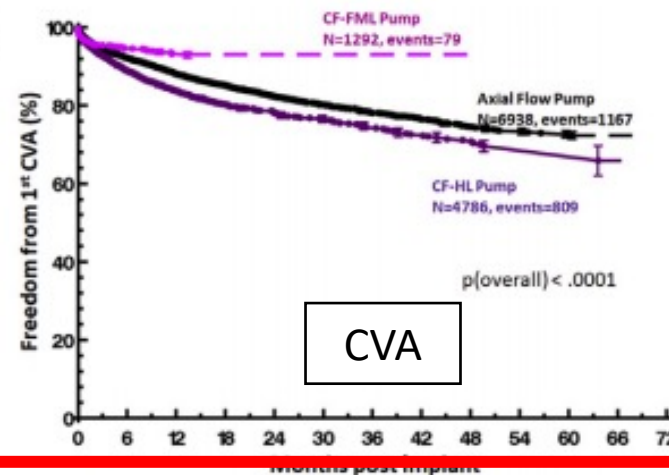
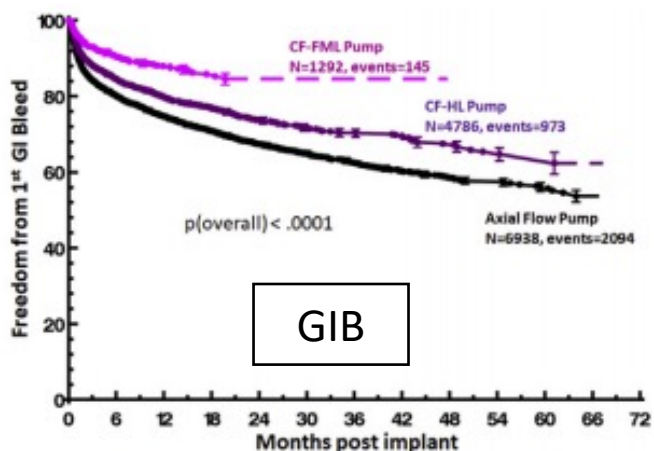


# Objectives

- Define the incidence of right heart failure
- Differentiate types of right ventricular assist devices
- Describe outcomes following RVAD implant

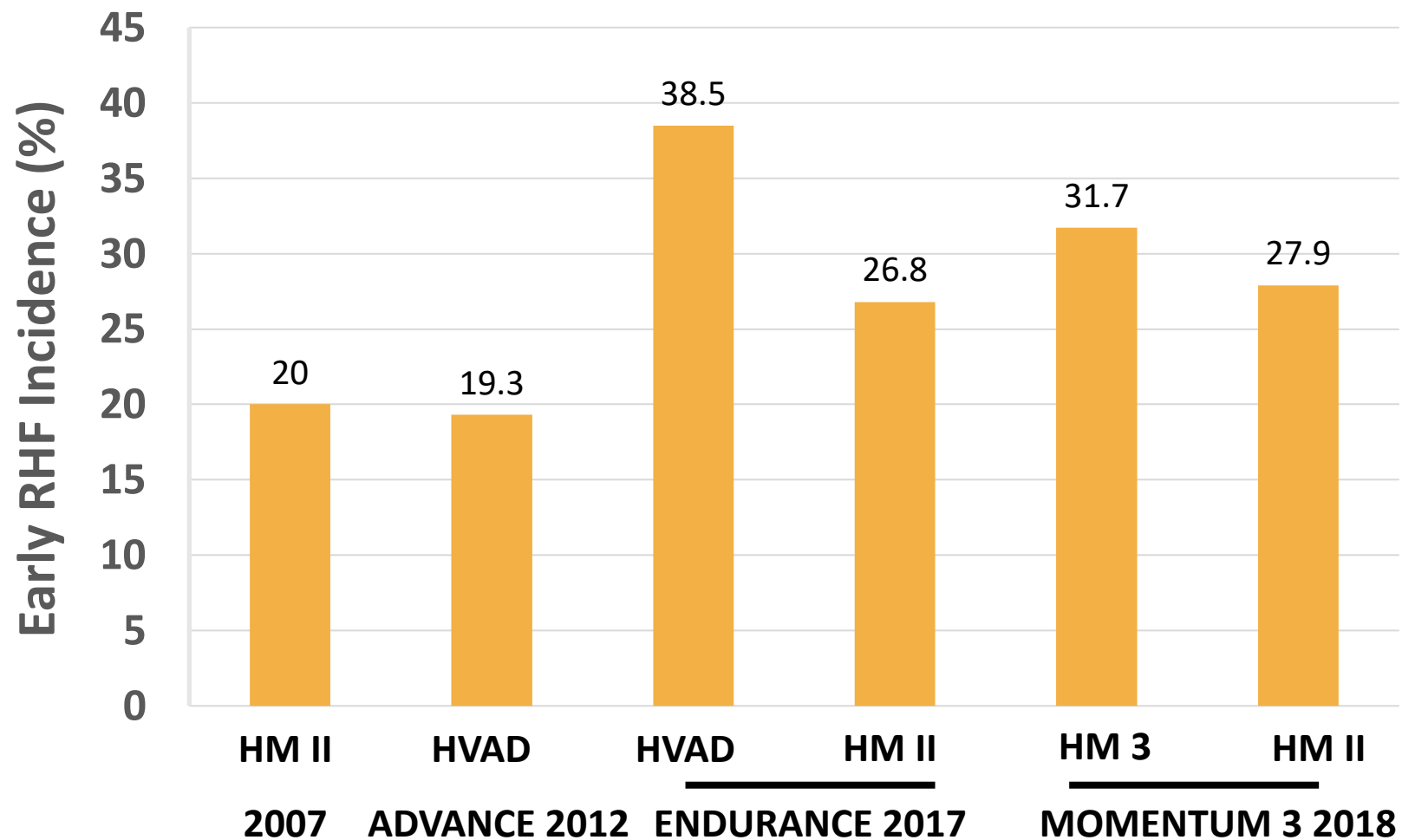


# Improving AE Profile with Current Technologies: Adverse events by device type





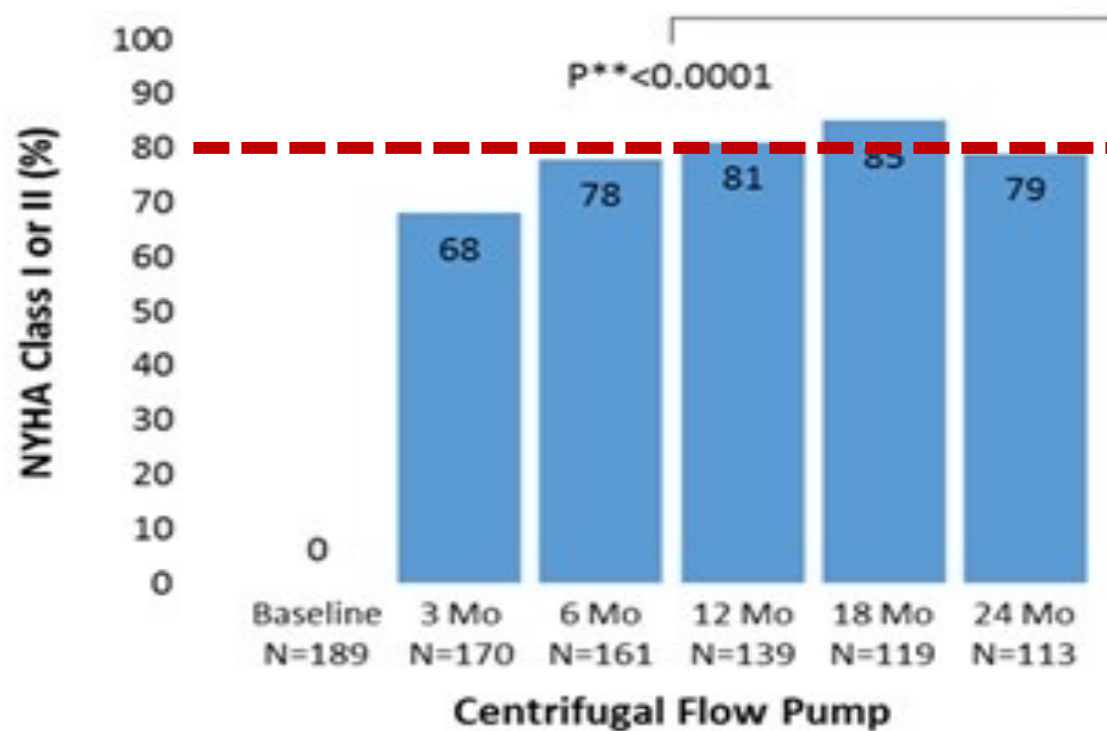
## Incidence of early RHF





# Functional capacity after LVAD implantation: 20% with persistent NYHA III/VI symptoms

Proportion of Patients who are NYHA I or II over Time





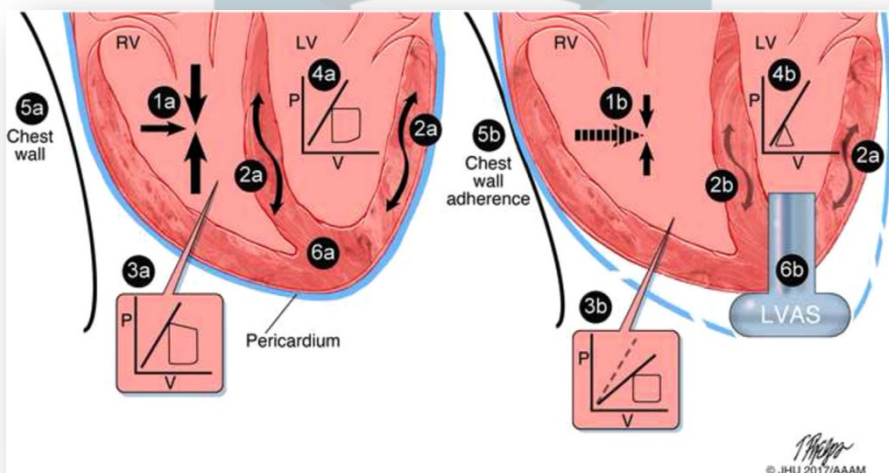
# The Vexing Problem of Right Heart Failure

- Given known worse survival of BiVAD recipients, there is *generally* a preference to avoid RVAD unless it is clearly necessary – ***inexact science***
- Ability to identify right heart failure (RHF) prior to or during LVAD implant that is severe enough to warrant an RVAD is **imprecise**
- Many patients with marginal RV function are deemed days to weeks after initial LVAD to warrant 2<sup>nd</sup> procedure – sequential RVAD
- Decision-making further complicated by choice of temporary or durable (*off-label*) RVAD, depending on expected duration of support
- ***No commercially available FDA approved DURABLE RVADs!***

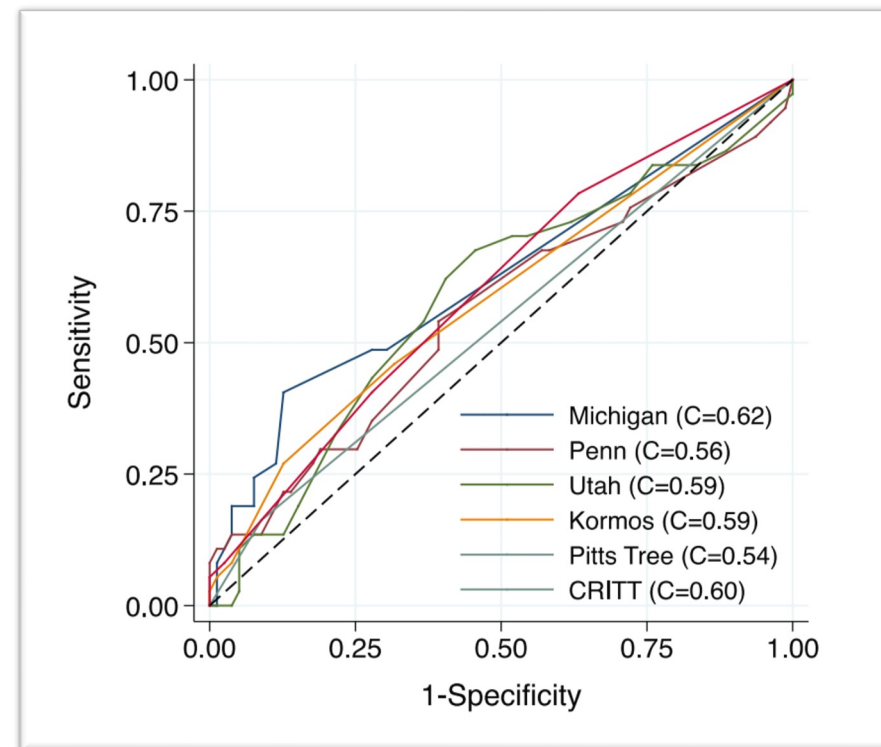




# Prediction: is really difficult!!



## ROC for RHF Models



AUC of 0.5 suggests no discrimination (**test not helpful**)

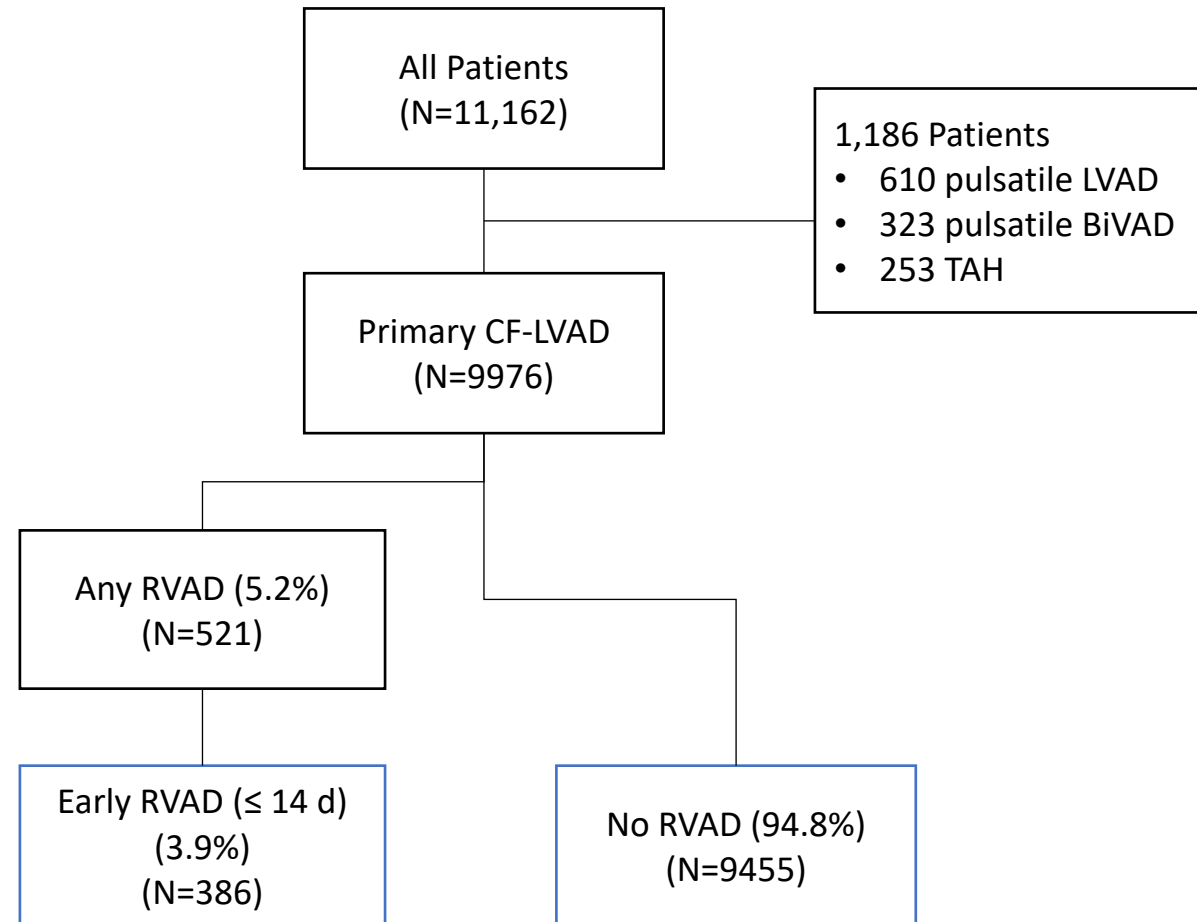
0.7 to 0.8 considered acceptable

0.8 to 0.9 considered excellent

> 0.9 considered outstanding.

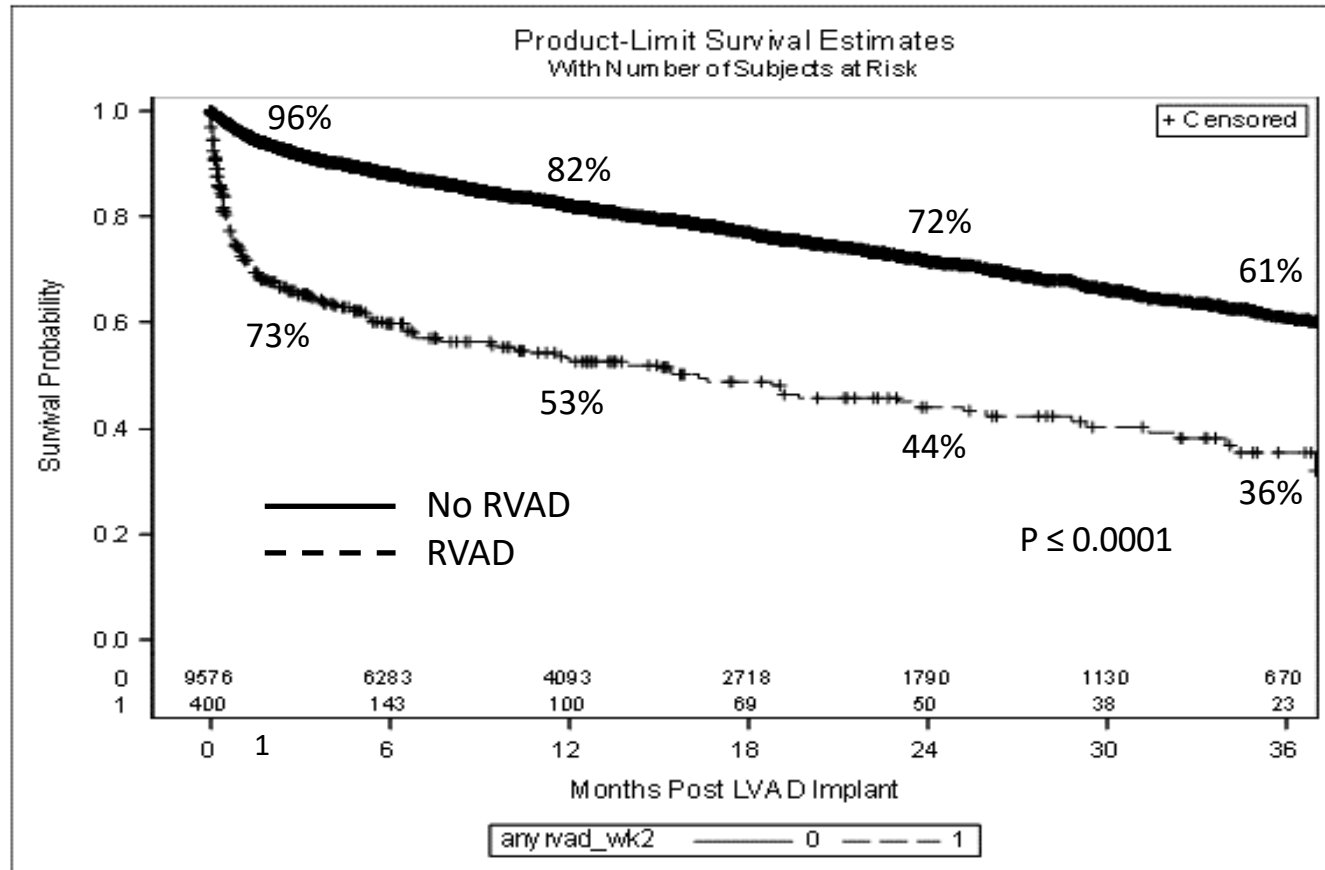


## INTERMACS study cohort (6/2006-3/2015)





## Survival for CF-LVAD recipients with and without early RVAD



	Hazard Ratio (95% CI)	P Value
Adjusted	<b>2.76</b> (2.34, 3.24)	<.0001

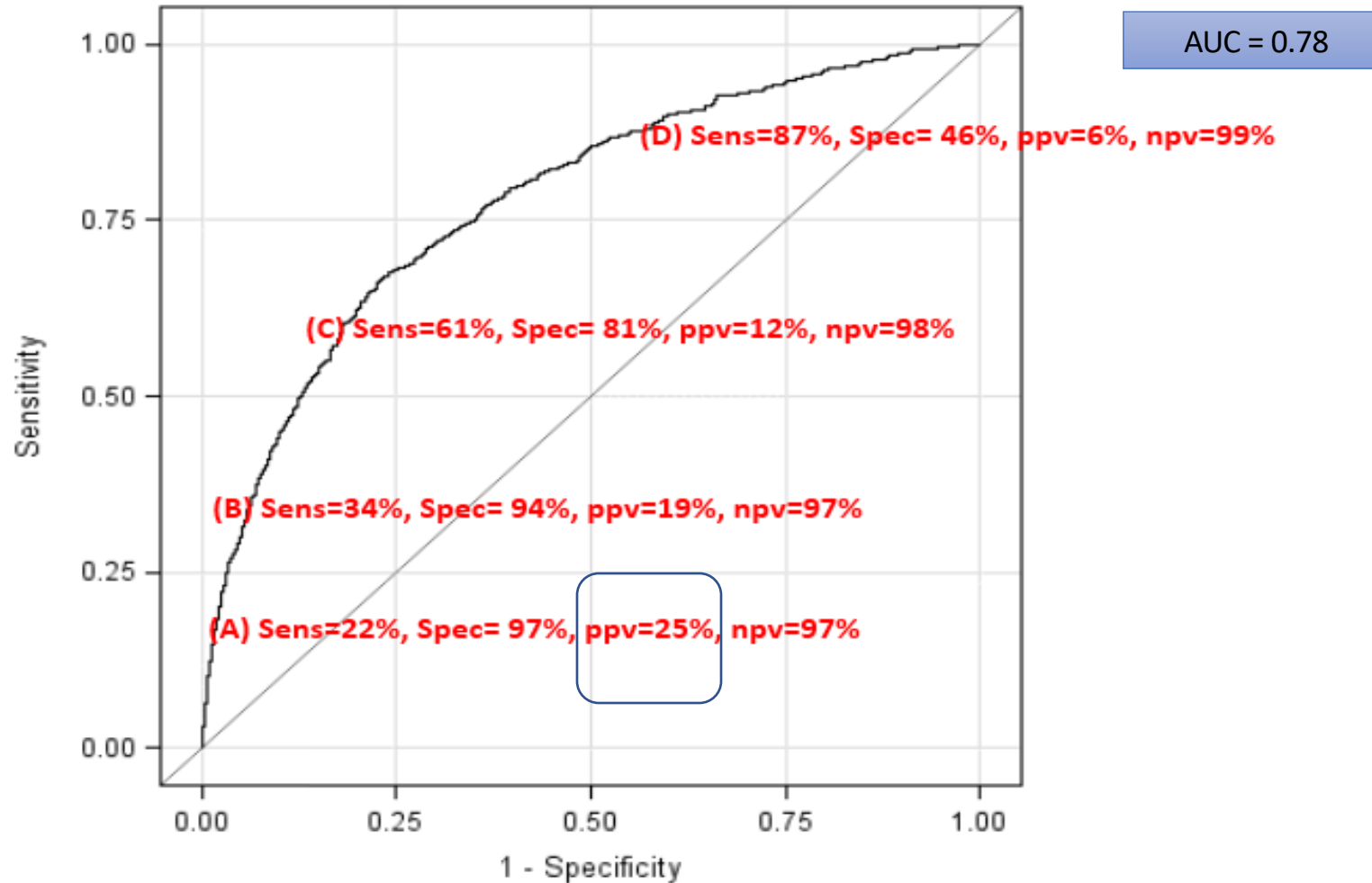


# Patient characteristics by prediction of risk

		Estimated probability of RVAD within 14 days of CF-LVAD			
		<1%	1-5%	5-10%	≥10%
TOTAL N		1359	6618	1304	695
Creatinine (mg/dL)	Median	1.2	1.3	1.4	1.5
Total Bili (mg/dL)	Median	0.8	1	1.5	2
INR	Median	1.1	1.2	1.4	1.4
WBC (x10 <sup>3</sup> /μL)	Median	7	7.6	9.2	11.6
RAP	Median	8	12.3	17	18.6
PA pulse pressure	Median	28	25	21.1	17.1
Stroke volume (x100)	Median	5.8	4.7	4.1	3.9
LVEDD	Median	7.2	6.8	6.5	6.2



## Receiver operating characteristic for early RVAD INTERMACS model

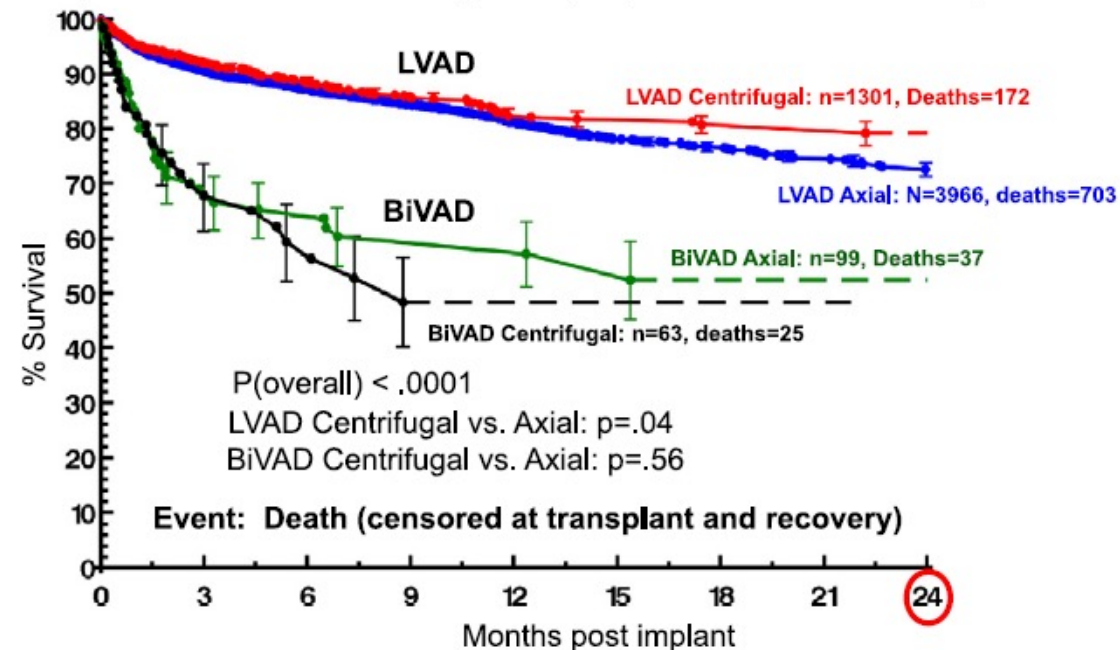




# Survival following LVAD and BiVAD implantation

Intermacs Continuous Flow LVAD/BiVAD Implants: 2008 – 2014, n=12030

Comparison of Axial vs. Centrifugal flow pumps: Nov 2012 – Dec 2014, n=5429



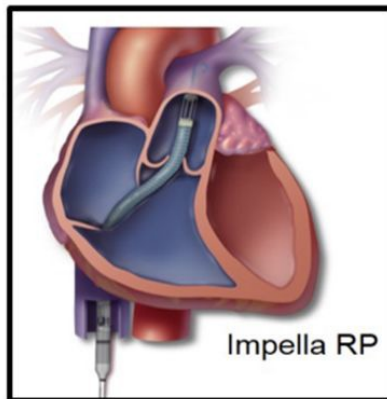
**Figure 7** Actuarial survival curve for continuous-flow LVAD and BiVAD patients, stratified by pump type. The depiction is as shown in Figure 6.





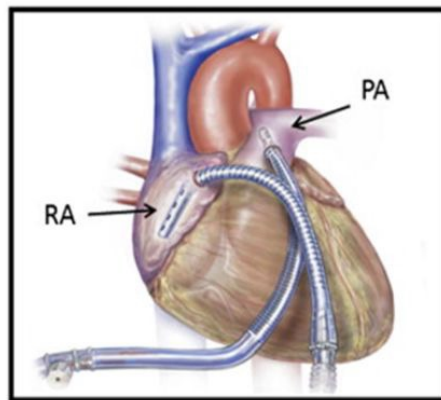
# Temporary mechanical circulatory support device options for acute right ventricular support

## Direct RV Bypass

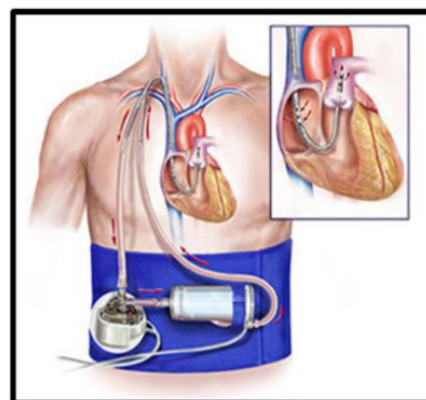


Impella RP

Axial Flow

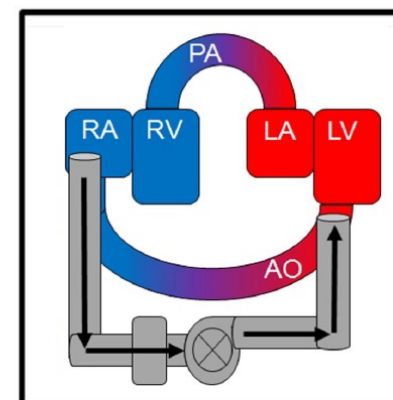


Tandem RVAD

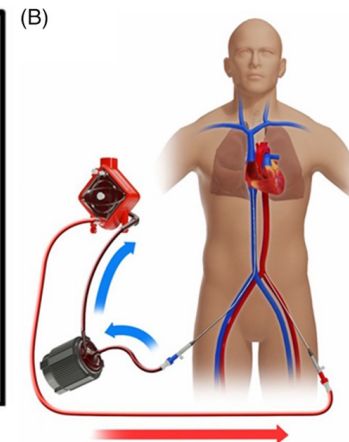


Protek Duo

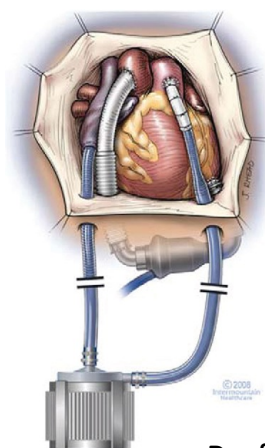
## Indirect RV Bypass



VA-ECMO



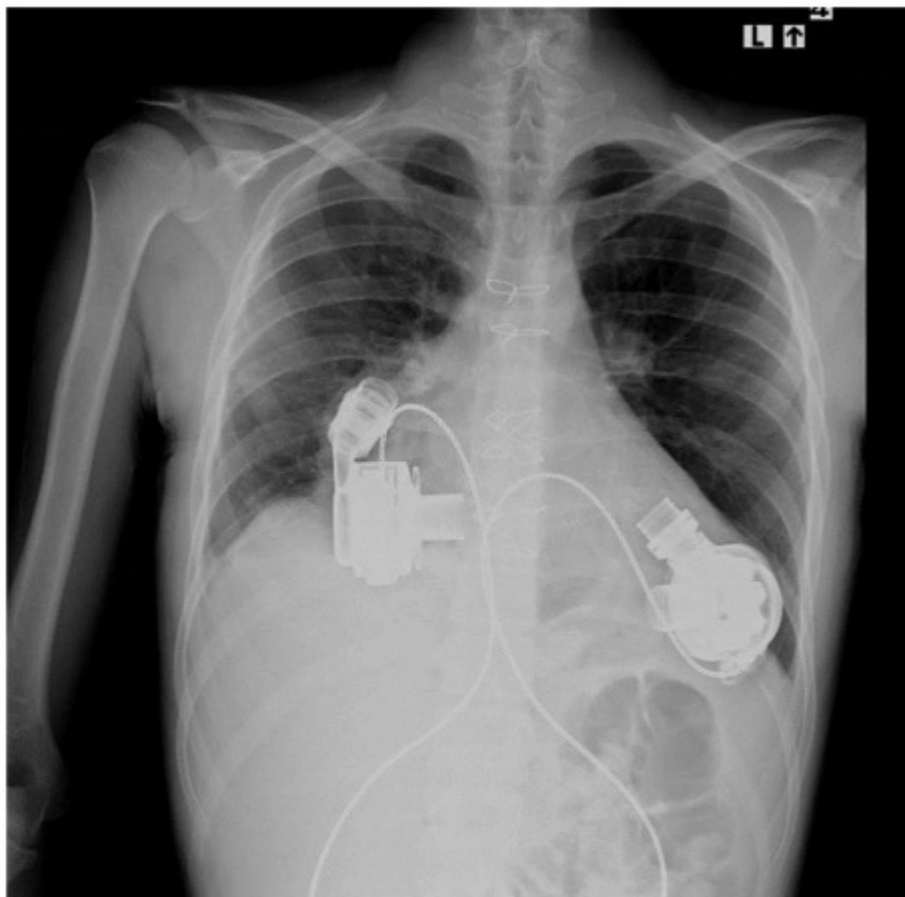
Extracorporeal Centrifugal Flow



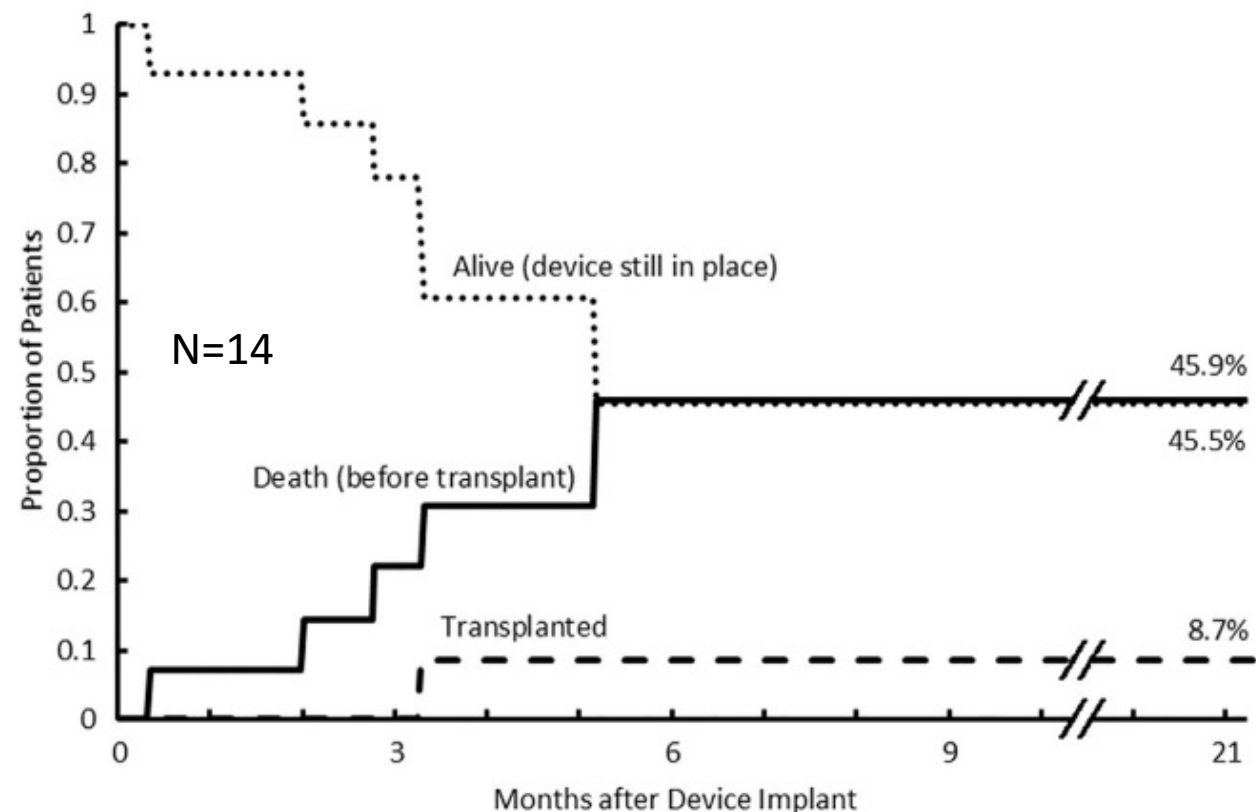




# Durable mechanical circulatory support device options for acute right ventricular support



**Figure 1** Chest X-ray of a patient displaying both VADs.

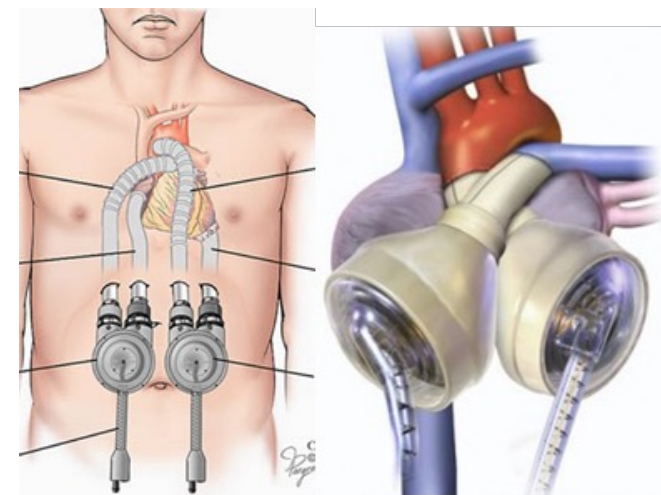




## Other durable mechanical circulatory support devices for right ventricular support

Device Type	STS InterMACS													
	2021 Q4		2022 Q1		2022 Q2		2022 Q3		2022 Q4		2023 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
LVAD	618	92.1 %	657	91.8 %	658	92.1 %	636	92.8 %	569	92.0 %	621	92.5 %	3759	92.2 %
BiVAD	50	7.4 %	55	7.6 %	54	7.5 %	48	7.0 %	47	7.6 %	46	6.8 %	300	7.3 %
TAH	3	0.4 %	3	0.4 %	2	0.2 %	1	0.1 %	2	0.3 %	4	0.5 %	15	0.3 %
TOTAL	671	100.0 %	715	100.0 %	714	100.0 %	685	100.0 %	618	100.0 %	671	100.0 %	4074	100.0 %

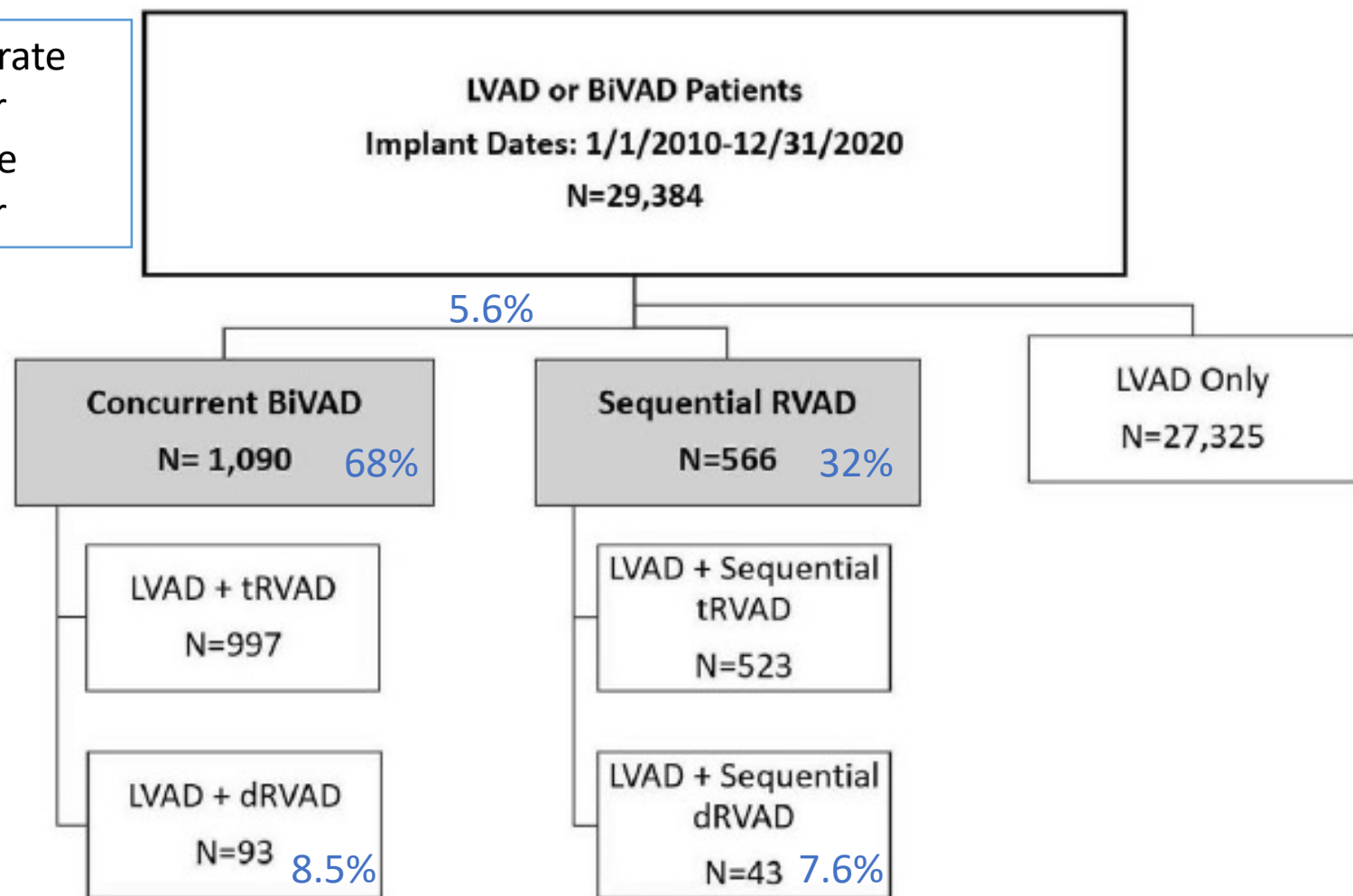
STS INTERMACS Quarterly Quality Assurance Report (2023 Q1)





# Updated Analysis of RVAD Use and Outcomes from INTERMACS: Focus on Timing and Device Type

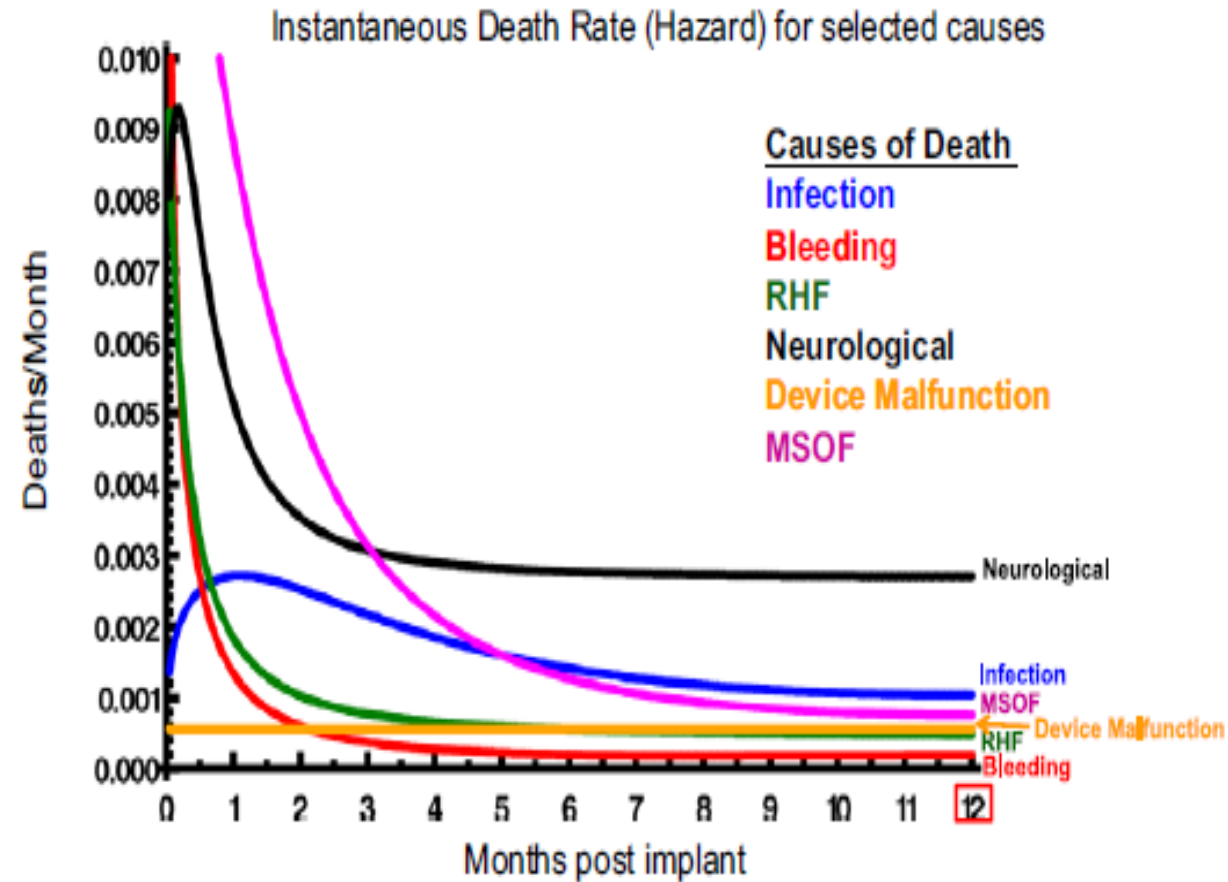
**Sequential** = separate surgical encounter  
**Concurrent** = same surgical encounter





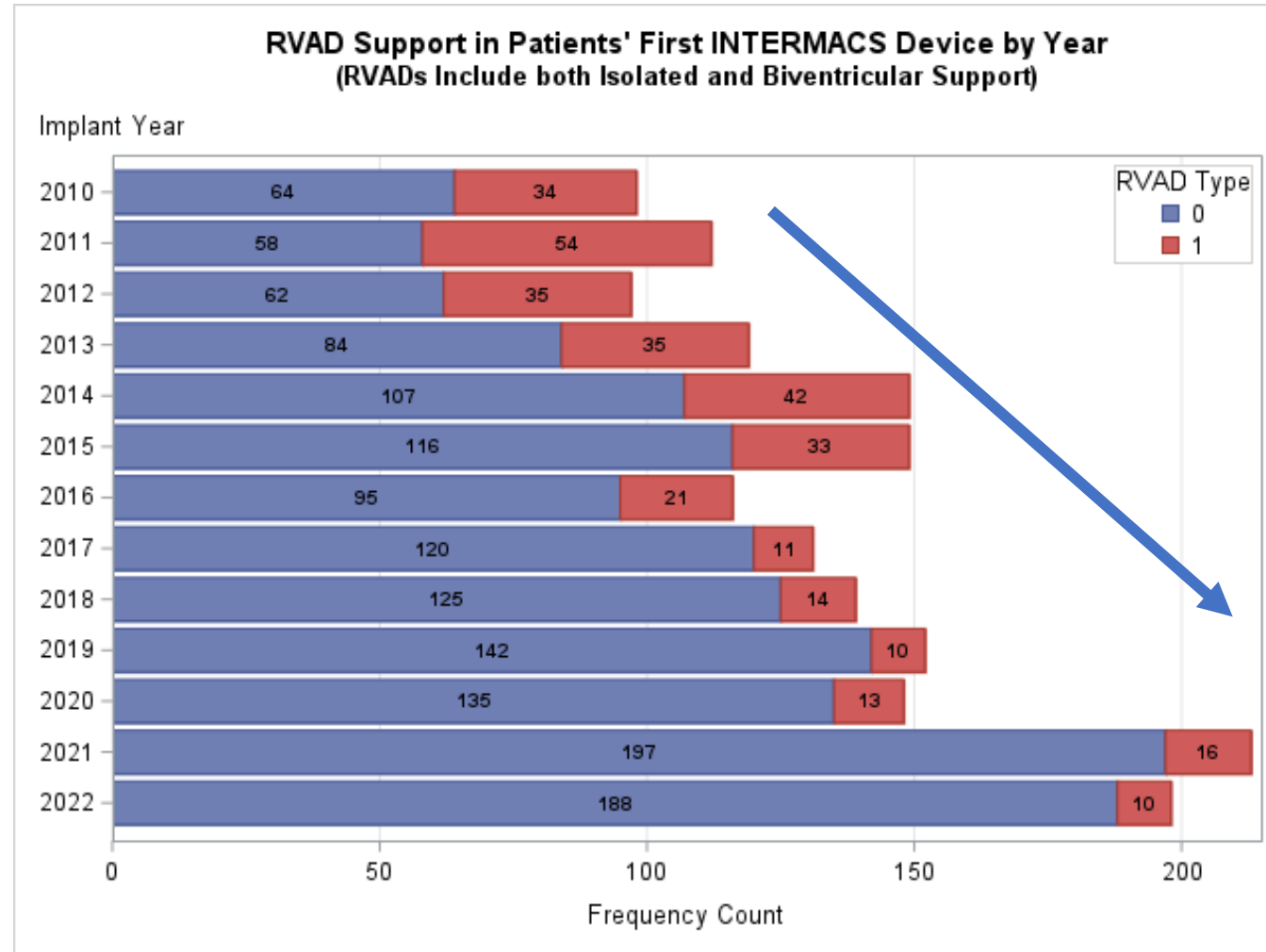
# Risk of death over time by cause

Interm@cs Continuous Flow LVAD/BiVAD Implants: 2008 – 2013, n = 9372



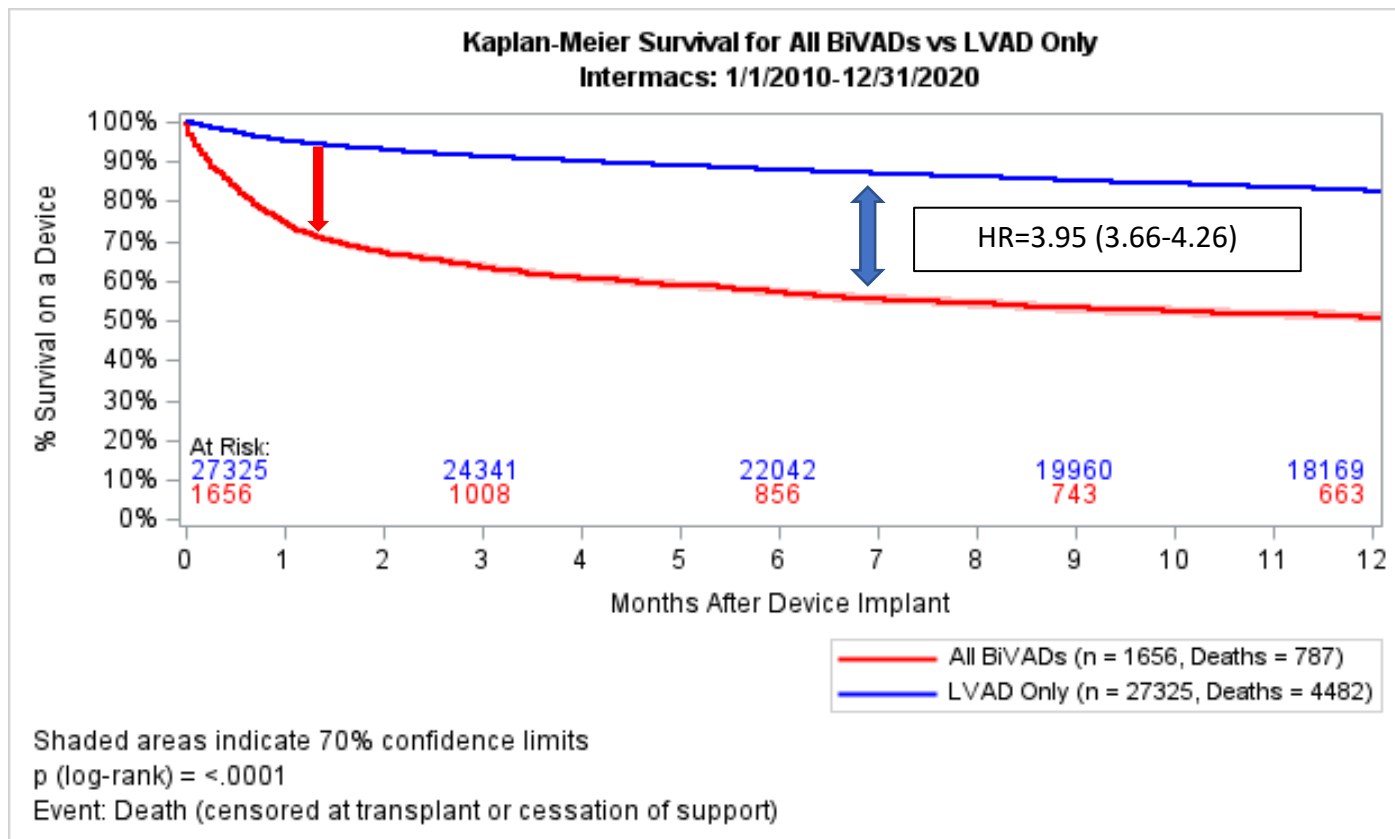


# Prevalence of RVAD use over time





# Worse Survival following BiVAD vs LVAD alone



Months after Device Implant	All BiVADs	LVAD Only
0	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	63.4% (62.2%-64.6%)	91.3% (91.1%-91.4%)
6	57.1% (55.9%-58.3%)	87.9% (87.7%-88.1%)
9	53.2% (51.9%-54.4%)	85.2% (85.0%-85.4%)
12	50.8% (49.6%-52.1%)	82.6% (82.4%-82.9%)

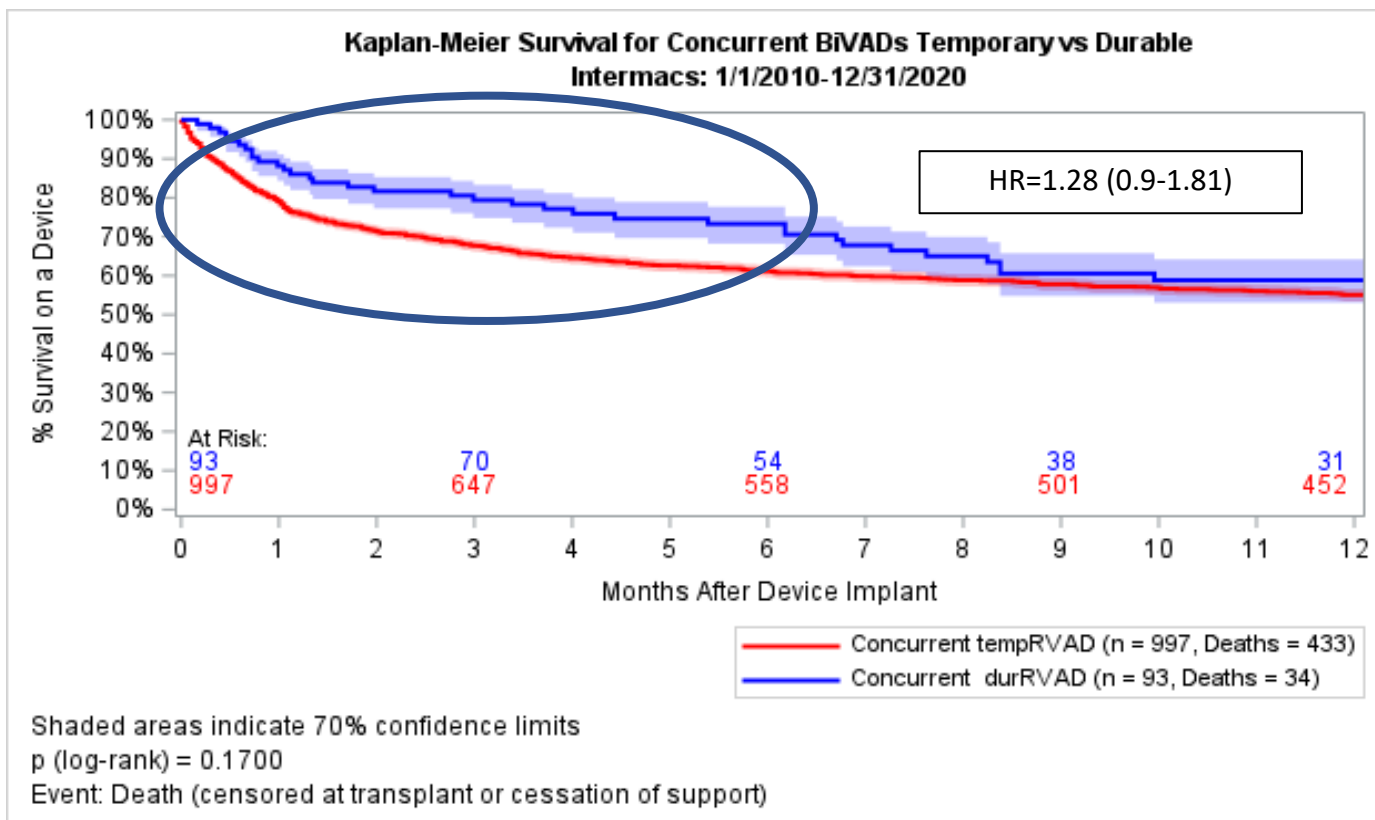
Missing: Comparison of survival by era





# Survival following Concurrent BiVAD: Temporary vs Durable

(Device Type: No survival difference)



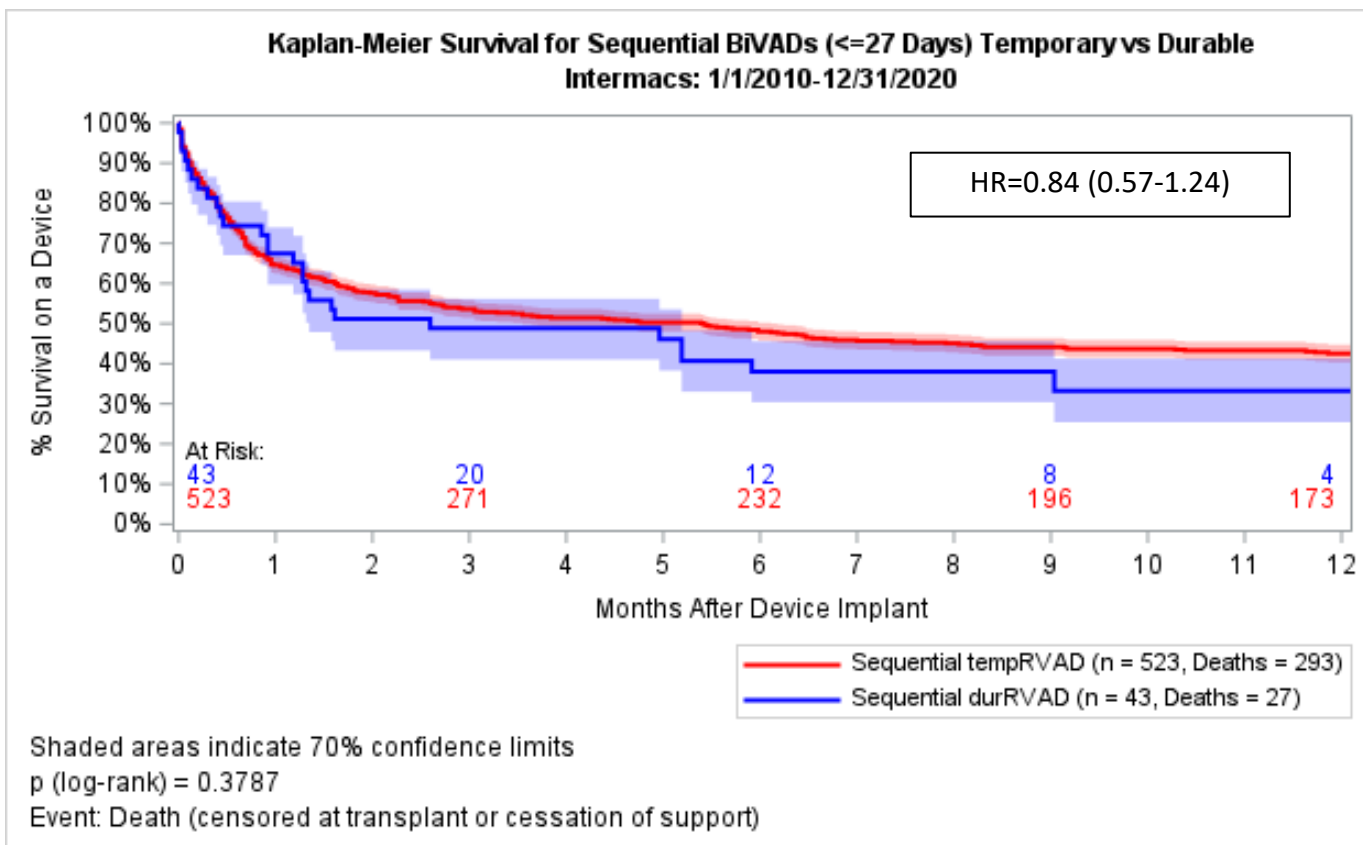
Months after Device Implant	Concurrent tempRVAD	Concurrent durRVAD
0	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	67.7% (66.2%-69.2%)	79.4% (74.8%-83.3%)
6	61.2% (59.6%-62.7%)	73.3% (68.2%-77.7%)
9	57.8% (56.2%-59.4%)	60.5% (54.8%-65.8%)
12	55.1% (53.4%-56.7%)	58.9% (53.1%-64.2%)

No statistical adjustment made for differing patient characteristics



# Survival Sequential BiVADs: *Temporary vs Durable* (Device Type: No survival difference)

Missing: Time to RVAD implant (hours, days, weeks?)



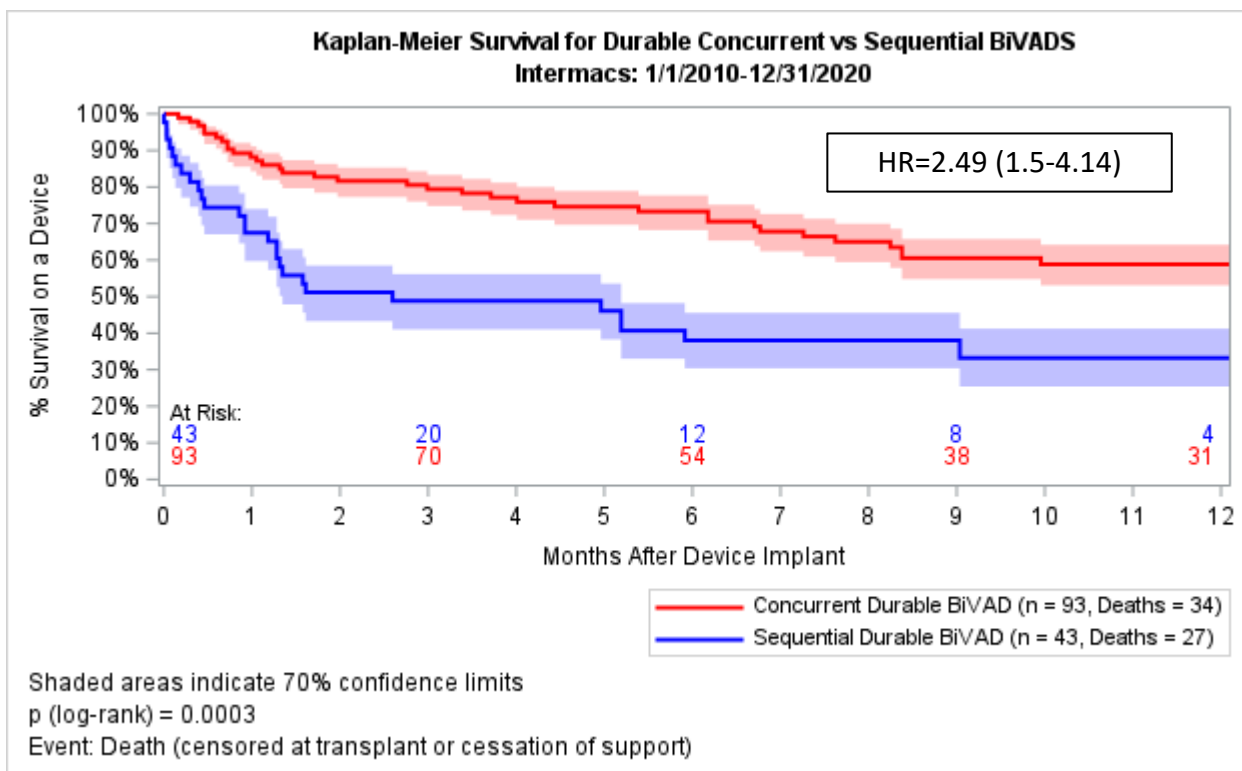
Months after Device Implant	Sequential tempRVAD	Sequential durRVAD
0	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	53.6% (51.4%-55.8%)	48.8% (41.0%-56.2%)
6	48.0% (45.8%-50.2%)	38.0% (30.4%-45.5%)
9	44.2% (42.0%-46.4%)	38.0% (30.4%-45.5%)
12	42.5% (40.3%-44.7%)	33.2% (25.4%-41.3%)





# Survival Durable BiVADs: **Concurrent vs Sequential**

(Device Timing: lower survival with delayed implant)

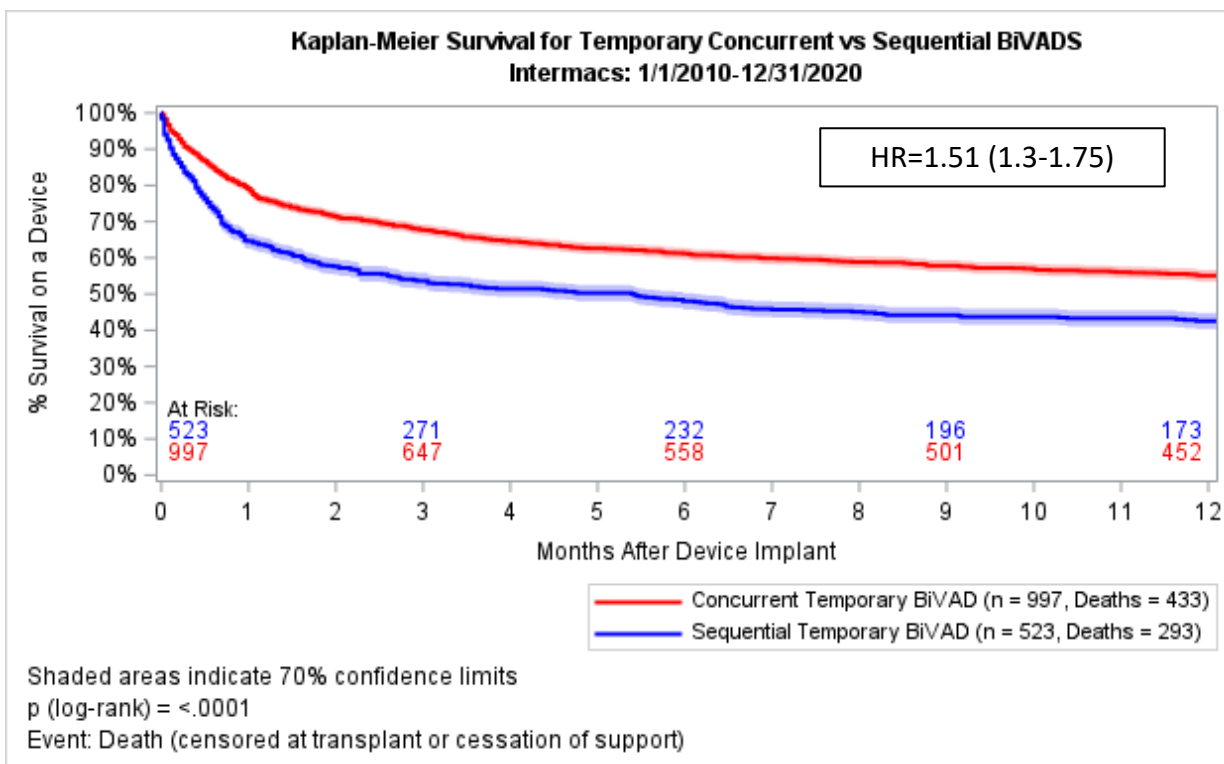


Months after Device Implant	Concurrent Durable BiVAD	Sequential Durable BiVAD
0	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	79.4% (74.8%-83.3%)	48.8% (41.0%-56.2%)
6	73.3% (68.2%-77.7%)	38.0% (30.4%-45.5%)
9	60.5% (54.8%-65.8%)	38.0% (30.4%-45.5%)
12	58.9% (53.1%-64.2%)	33.2% (25.4%-41.3%)



# Survival Temporary BiVADs: **Concurrent vs Sequential**

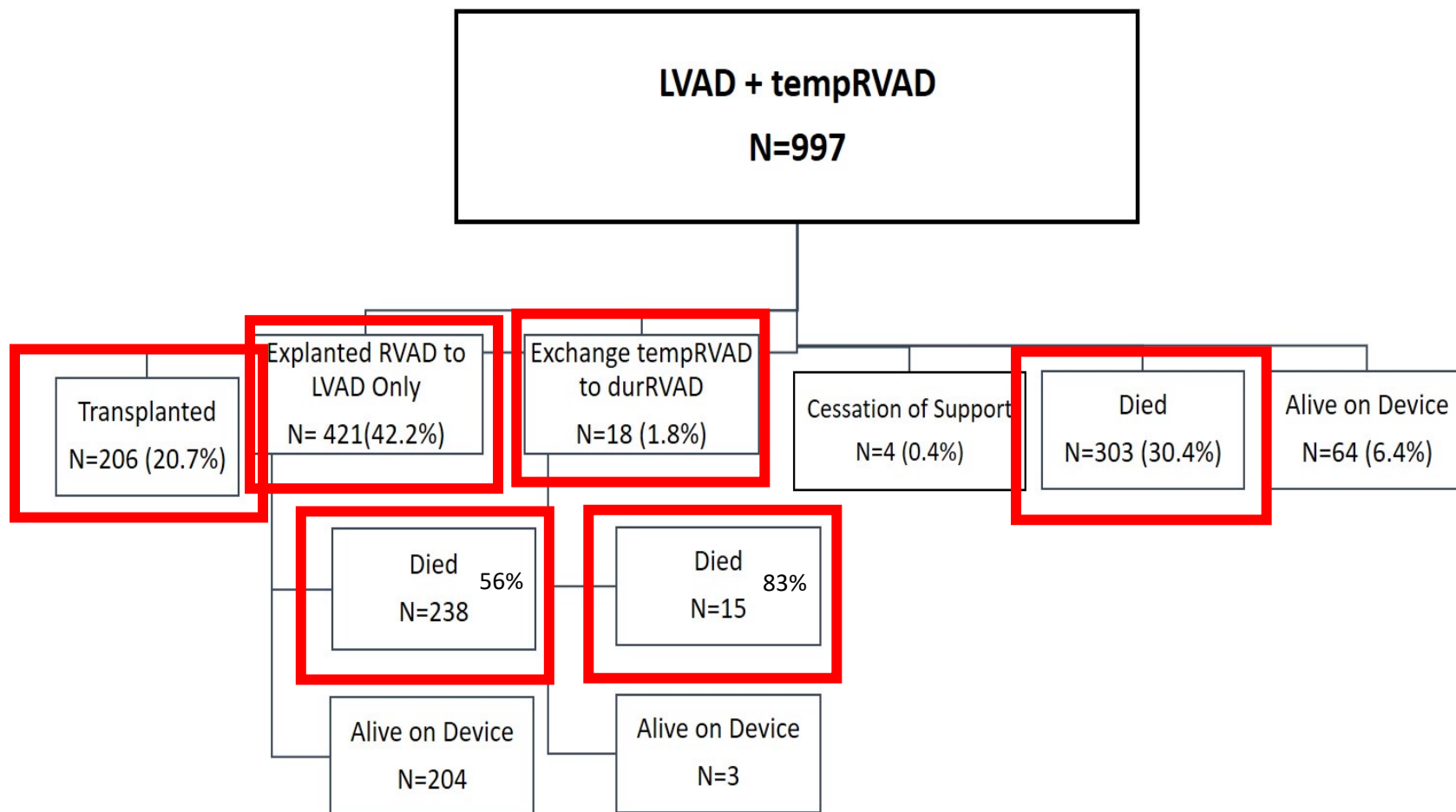
(Device Timing: lower survival with delayed implant)



Months after Device Implant	Concurrent Temporary BiVAD	Sequential Temporary BiVAD
0	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	67.7% (66.2%-69.2%)	53.6% (51.4%-55.8%)
6	61.2% (59.6%-62.7%)	48.0% (45.8%-50.2%)
9	57.8% (56.2%-59.4%)	44.2% (42.0%-46.4%)
12	55.1% (53.4%-56.7%)	42.5% (40.3%-44.7%)



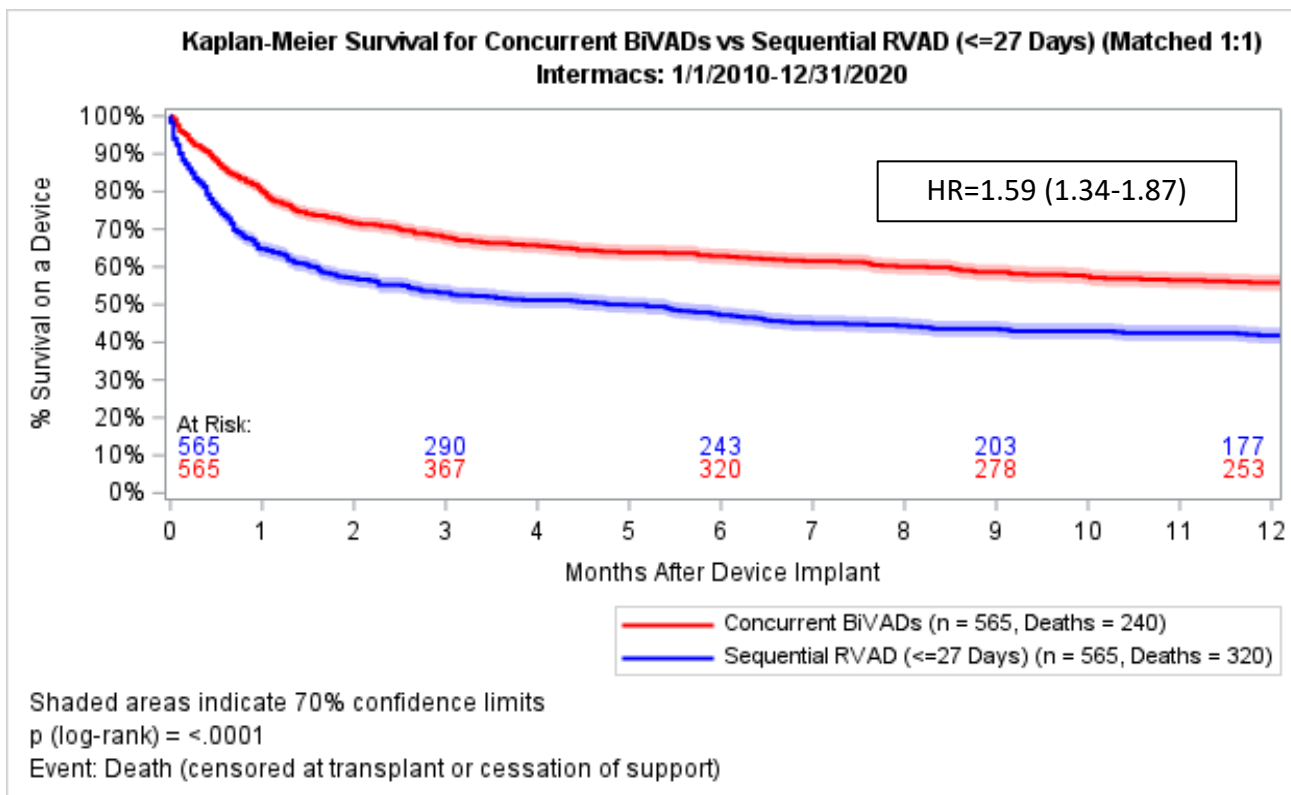
# Outcomes in temporary RVAD recipients





# Survival BiVADs: Concurrent vs Sequential

## Adjusted for baseline characteristics (Propensity Matched)



Months after Device Implant	Concurrent BiVADs	Sequential RVAD (<=27 Days)
0	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	67.8% (65.8%-69.7%)	53.2% (51.0%-55.3%)
6	62.9% (60.8%-64.9%)	47.2% (45.0%-49.3%)
9	58.6% (56.5%-60.7%)	43.6% (41.5%-45.7%)
12	55.8% (53.6%-57.9%)	41.8% (39.7%-43.9%)

Missing: timing of subsequent operation



# Concurrent vs Sequential: 3m Adverse Events Temporary RVADs





**TABLE 3 Adverse Event Profile: Concurrent vs Sequential Biventricular Assist Devices With the Use of Temporary Right Ventricular Assist Device**

Adverse Event	Concurrent BiVAD with Temporary RVAD (n = 997)		Sequential BiVAD with Temporary RVAD (n = 523)		P Value
	Episodes, n (%)	Rate (per 100 patient-months)	Episodes, n (%)	Rate (per 100 patient-months)	
Early (≤3 months)					
Bleeding	956 (51.5)	42.2	501 (52.0)	50.28 ↑	<.01
Device malfunction/pump thrombosis	91 (8.2)	4.02	70 (12.4)	7.02	<.1
Infection	691 (42.6)	30.51	385 (43.8)	38.64 ↑	<.01
Neurologic dysfunction	171 (14.7)	7.55	115 (19.5)	11.54 ↑	<.01
Renal dysfunction	284 (26.3)	12.54	261 (45.7)	26.19 ↑	<.01



# Concurrent vs Sequential 3m Adverse Events: Durable RVADs

**TABLE 2 Adverse Event Profile: Concurrent vs Sequential Biventricular Assist Devices With the Use of Durable Right Ventricular Assist Device**

Adverse Events	Concurrent BiVAD With Durable RVAD (n = 93)		Sequential BiVAD With Durable RVAD (n = 43)		P Value
	Episodes, n (%)	Rate (per 100 patient-months)	Episodes, n (%)	Rate (per 100 patient-months)	
Early ( $\leq 3$ months)					
Bleeding	54 (36.6)	22.59	44 (65.1)	55.24 	<.01
Device malfunction/pump thrombosis	26 (22.6)	10.88	10 (20.9)	12.56	.7
Infection	60 (43.0)	25.10	41 (58.1)	51.48 	<.01
Neurologic dysfunction	21 (20.4)	8.79	14 (23.3)	17.58 	.004
Renal dysfunction	16 (17.2)	6.69	25 (51.2)	31.39 	<.01



# Conclusions

- Incidence of RVAD use: 5.6% - stable over time
- Majority (68%) are concurrent with index surgery
- Majority (91%) temporary
- Mortality high in RVAD recipients (6m month survival 63%) – 60% more likely to die than those with isolated LVAD within a year
- AE (bleeding, cva, infection, renal failure) more common in RVAD recipients

## Questions?

Michael Kiernan, MD, MS, MBA

Associate Professor of Medicine, TUSM

Associate Chief, Division of Cardiology, Tufts Medical Center