



Survival and Predictors of Mortality In Patients Undergoing RVAD Explant in IMACS

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Relevant Disclosures

I will not discuss off label use and/or investigational use of any drugs/devices.

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Introduction

- Patients with right heart failure (RHF) requiring mechanical RV support after cfLVAD have survivals of only 58% at 1 year¹
- There is an insufficient understanding of the frequency of RVAD explant and cfLVAD patient survival after RVAD explant



Purpose

The aims of this analysis are as follows:

- 1) To gain a better understanding of the indications for RVAD explant within IMACS, a global LVAD registry
- 2) To examine survival according to indication for RVAD explant
- 3) To identify predictors of mortality after RVAD explant



Methods

- Patients enrolled into IMACS between January 2013-September 2017 (n=16,482) undergoing primary continuous flow LVAD were eligible for enrollment
- Patients were grouped according to need for RVAD explant (Exp) for nontransplant indications vs. continued BiVAD vs. RVAD inactivation for any cause
- Indications for RVAD explant could include:
 - Recovery
 - Device Dysfunction: urgent, non-urgent
 - Pump Thrombosis: urgent, elective
 - Other

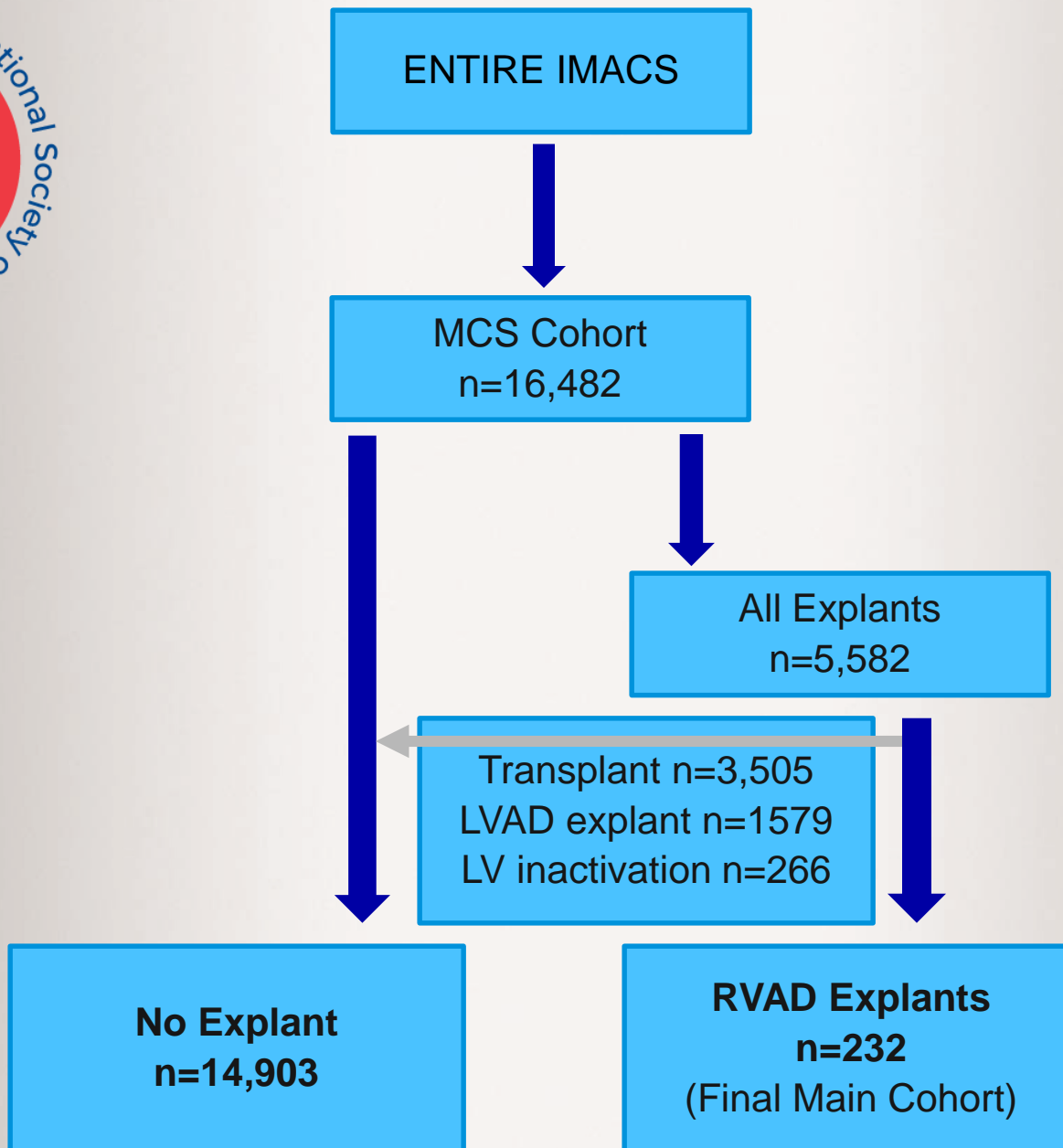


Statistical Methods

- Exp and nonEXP groups were compared
 - Frequencies: Chi Square
 - Continuous data: t-testing or Mann-Whitney U test according to data distribution
- Survival: estimated using Kaplan-Meier methods
 - Log rank comparison between Exp and nonEXP
- Cox Regression: used to identify correlates of mortality ($p < 0.05$ significant) in patients undergoing Explant



Results



Preoperative Characteristics and Demographics

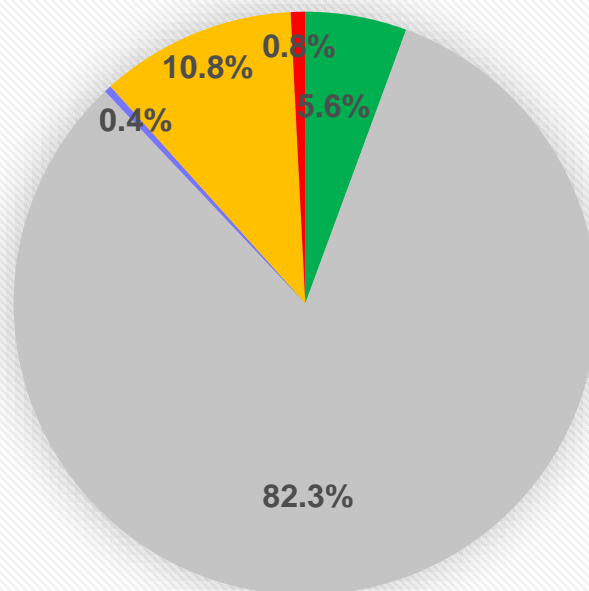
	Total Cohort (n=16482)	No Device Explant (n=14,903)	RV Device Explant (n=1,579)	P-value
Region of World, n(%)				
Americans	13646 (83%)	13442 (83%)	233 (92%)	0.001
Asia-Pacific	808 (5.0%)	802 (4.9%)	8 (3.1%)	
Europe	2028 (12%)	2010 (12.2%)	13 (5.1%)	
Age, yrs	55±11.2	55.3±14.2	52.7±15.9	0.027
Male sex, n(%)	12954 (79%)	12787(79%)	187 (74%)	0.11
BMI	27.86±5.2	27.8±6.9	28.3±7.5	0.26
Prior Sternotomy, n(%)	4672 (30%)	4598 (30%)	106 (45%)	<0.001
BTT, listed, n(%)	4843 (29%)	4789 (30%)	63 (25%)	0.11
INTERMACS Profile 1-2, n(%)	8419(51%)	8238 (51%)	201 (79%)	<0.001
Creatinine, mg/dL	1.37±1.0	1.36±0.68	1.47±1.05	0.23
Bilirubin, mg/dL	1.00 [0.64, 1.60]	1.00 [0.63,1.60]	0.90 [0.60,1.50]	<0.0001
Albumin, g/dL	3.43±0.01	3.45±0.69	3.14±0.64	<0.0001
Dialysis preVAD, n(%)	514 (3.1%)	496 (3.1%)	22 (8.7%)	<0.0001
Temporary Circulatory Support, n(%)				
ECMO	1136 (7.1%)	1088 (6.9%)	57 (24%)	<0.0001
IABP	4603 (29%)	4499 (28%)	109 (45%)	<0.0001
LVAD Device type, n(%)				
Centrifugal Flow	6154 (37%)	6056 (37%)	84 (34%)	0.28
Axial Flow	10325 (63%)	10160 (63%)	163 (66%)	
Length of stay, months	0.82 [0.76, 1.2]	0.69 [0.46,1.1]	1.1549 [0.79, 1.77]	<0.0001
Concomitant Surgery, n(%)	6822 (41%)	6651 (40%)	194 (76%)	<0.0001
Time on support, months	12.8 [5.1,25.4] (mean 16.6)	13 [5.4,25] (mean 17)	22 [12,35] (mean 13)	<0.001



Indications For RVAD Explantation

Explant-Inactivation Reason

N=232 RVAD
explants

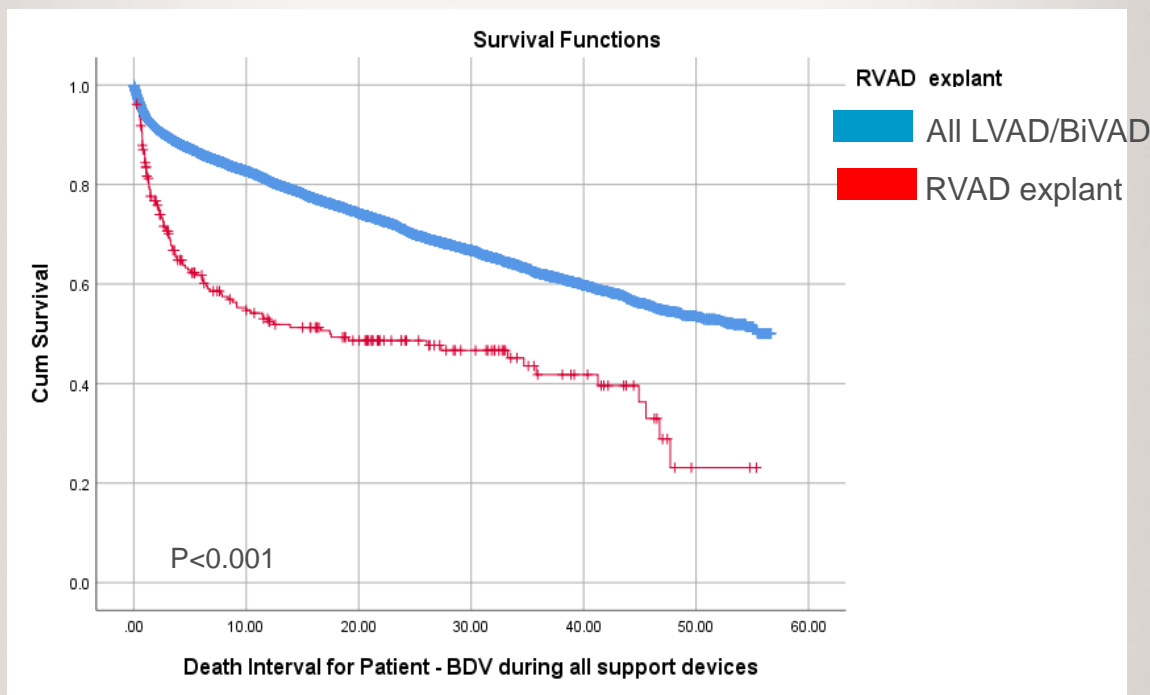


■ Device Malfunction ■ Xplant Recovery ■ PT ■ Inactivation Recovery ■ Other

Inactivation= device left in place but inactivated due to the single indication of recovery; all other categories above required RVAD explant



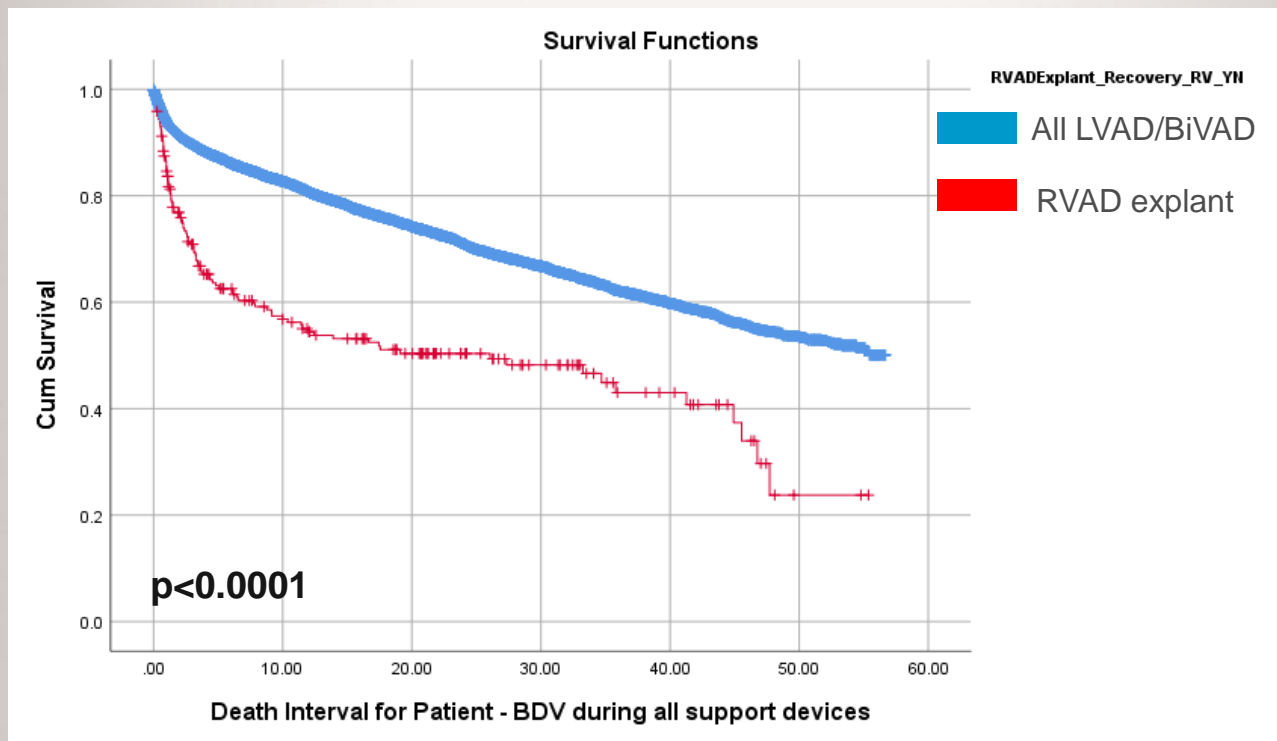
Survival: RVAD explants (n=232) vs LVAD and BiVADs on Support



	1 Month	1 Year	3 Years
RVAD explant	85±2.4% (n=232)	52±3.5% (n=192)	42±4.2%
All LVADs/BiVADs on support	94±0.2% (n=16250)	81±0.3% (n=14998)	62±0.6% (n=8567)



Survival According to RVAD Explant or Inactivation for RV Recovery (n=216)



Characteristics and Demographics according to status after RVAD Explant

Baseline characteristics	Alive (n= 115)	Dead (n=117)	p
Age at Implant (yrs)	51.5±15.2	56.7±13.7	0.006
Body Mass Index	27.7±7.6	29.2±7	0.12
Pulmonary artery systolic pressure(mmHg)	45.8±13.2 (n=106)	51.12±16 (n=101)	0.009
Mean RA pressure(mmHg)	16.6±10.4 (n=71)	16±8.5 (n=82)	0.68
PAWP(mmHg)	25. 3±8.6 (n=80)	26.8±9.4 (n=80)	0.30
Cardiac output (L/min)	4±1.2 (n=92)	4 ±1.5 (n=95)	0.74
Albumin (g/dL)	3.2±0.6 (n=114)	3.1±0.7 (n=111)	0.54
Alanine Aminotransferase (ALT) (u/L)	144.8±530 (n=113)	144.8±373 (n=112)	1.0
INR	1.4±0.3 (n=109)	1.4±0.3 (n=105)	0.30
Total Bilirubin (mg/dL)	1.8±1.2 (n=113)	2.2±3 (n=111)	0.20
Creatinine (mg/dL)	1.4±0.7	1.7±1.3	0.035
Length of stay from implant to discharge (months)	1.6±1.12 (n=95)	1.4 ±1 (n=100)	0.37





Multivariate Predictors of Mortality in those undergoing RVAD explant

Variable	Hazard Ratio	p
Age at Implant	1.016 per year	0.058
PA systolic pressure	1.03 per mmHg	0.002
Creatinine	1.001 per mg/dL	0.14
INR	0.422	0.052
Albumin	0.77 per g/dL	0.95
ALT	1.001 per IU	0.025
Female	1.2	0.68



Conclusions

- Patients undergoing RVAD explant were very ill in the preoperative period- high use of dialysis, ECMO, IABP support
- The majority (82%) of RVAD explants in IMACS were performed for RV myocardial recovery
- Despite the “recovered RV,” survival is worse in patients on BiVAD support who underwent RVAD explant compared to the general LVAD population.



Conclusions

- Patients with elevated PA pressures, hepatic insufficiency and/or coagulopathy in the preoperative prior were more likely to die after RVAD explant.
- These findings may suggest that RV recovery was likely incomplete/nondurable prior to RVAD explant.
 - Eligible patients on BiVAD- even those with signs of RV recovery- may be better served with transplant than RVAD explant.



Limitations

- This is a Registry study
 - Limited detail on “Other” indications for explant
 - Lack information on RVAD type
 - Thresholds for explant indications and urgent explantation vary among institutions and countries



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