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Impact of Concurrent Surgical Valvular Procedures in Patients Receiving Continuous-flow LVADS

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Disclosure

- Research Grant Thoratec, Heartware

Background

- Increasing utilization of LVADs for end-stage heart failure
- Coexisting heart valve disease can complicate the efficient functioning of LVADs
- New valve pathophysiology can also occur after LVAD placement, especially with the aortic valve

Background

- Indications and subsequent benefits of performing valvular procedures at the time of LVAD implant in these patients are unclear

- Few single center studies with no consistent conclusions

Objective

- Evaluate clinical outcomes of performing concurrent surgical valvular procedures in a large cohort of patients receiving continuous-flow LVADS

Patients and Methods

- Retrospective review of 1106 patients supported by the HeartMate II LVAD as bridge to transplant (BTT) and destination therapy (DT) in the clinical trial
- 470 BTT and 630 DT patients at 44 centers
- Patients divided into 2 groups – HM II alone (n=641) and HM II with concurrent valvular procedures (n=242)

Summary of Cardiac Procedures

	Number of Procedures
Patients with Valvular Procedures	242
Only Tricuspid	124
Only Aortic	55
Only Mitral	26
Tricuspid + Aortic	18
Tricuspid + Mitral	12
Aortic + Mitral	5
Tricuspid+Mitral+Aortic	2
PFO Closure	61
Removal of LV Thrombus	8
LV Aneurysm Resection/Repair	5
Insert ICD/Repair ICD	8
CABG	22
RF Ablation	3
RA Thrombectomy	4
Lysis of cardiac adhesiions	3

Patient Demographics: HMII vs. HMII+AVP

Variable of Interest	HMII Alone (n=641)	HMII + AV Procedures (n=55)	p-value
Age (years)	58 ± 14	*66 + 11*	*< 0.001*
Female (%)	142 (22%)	*5 (9%)*	*0.024*
Ischemic (%)	336 (52%)	32 (58%)	0.482
Mechanical ventilation (%)	31 (5%)	2 (4%)	1.000
IABP	188 (29%)	13 (24%)	0.440
Inotrope Use	546 (85%)	*39 (71%)*	*0.011*
DT(%)	364 (57%)	*39 (71%)*	*0.046*
CVP (mm/Hg)	12.3 ± 6.4	12.0 ± 5.5	0.972
PVR	3.22 ± 1.75	3.25 ± 1.66	0.767
PCWP	24.6 ± 8.8	24.0 ± 7.2	0.865
RVSWI	576 ± 303	583 ± 304	0.825
CVP/PCWP	0.52 ± 0.38	0.49 ± 0.19	0.745
INR	1.33 ± 0.62	1.32 ± 0.38	0.477
Creatinine (mg/dL)	1.45 ± 0.52	1.54 ± 0.55	0.212
CI	2.03 ± 0.64	2.01 ± 0.51	0.666
BUN	31.3 ± 17.5	*35.1 ± 17,1*	*0.079*
AST	57 ± 156	34 ± 24	0.149
L-M Score	9.72 ± 5.38	10.8 ± 5.6	0.224

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Patient Demographics: HMII vs. HMII+TVP

Variable of Interest	HMII Alone (n=641)	HMII + TVP (n=124)	p-value
Age (years)	58 ± 14	57.3 ± 14.4	0.768
Female (%)	142 (22%)	28 (23%)	0.074
Ischemic (%)	336 (52%)	58 (47%)	0.280
Mechanical ventilation (%)	31 (5%)	3 (2%)	0.340
IABP	188 (29%)	38 (31%)	0.749
Inotrope Use	546 (85%)	98 (79%)	0.106
DT(%)	364 (57%)	73 (59%)	0.693
CVP (mm/Hg)	12.3 ± 6.4	*14.4 ± 6.8*	*0.002*
PVR	3.22 ± 1.75	3.28 ± 1.97	0.951
PCWP	24.6 ± 8.8	24.7 ± 7.4	0.693
RVSWI	576 ± 303	*482 ± 289*	*0.001*
CVP/PCWP	0.52 ± 0.38	*0.59 ± 0.24*	*0.003*
INR	1.33 ± 0.62	1.34 ± 0.28	0.952
Creatinine (mg/dL)	1.45 ± 0.52	1.53 ± 0.60	0.264
CI	2.03 ± 0.64	1.98 ± 0.63	0.493
BUN	31.3 ± 17.5	*39.7 ± 31.2*	*0.008*
AST	57 ± 156	53 ± 107	0.825
L-M Score	9.72 ± 5.38	*10.8 ± 5.2*	*0.070*

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Concurrent Valvular Procedures: Outcomes

Patients	n	30-day Mortality	180-day Mortality
HMII alone	641	31 (4.8%)	102 (15.9%)
HMII + valve*	242	25 (10.3%)	51 (21.0%)
Aortic Only	55	6 (10.9%)	16 (29.1%)*
Mitral Only	26	3 (11.5%)	6 (23.1%)
Tricuspid Only	124	11 (8.9%)	21 (16.9%)
2 or more valve procedures	37	5 (13.5%)*	8 (22%)
HMII + other	90	8 (8.9%)	15 (16.7%)
HMII + PFO	61	4 (6.6%)	9 (14.8%)

**** p< 0.05; ** p< 0.01; *** p < 0.001 relative to no concurrent procedures***

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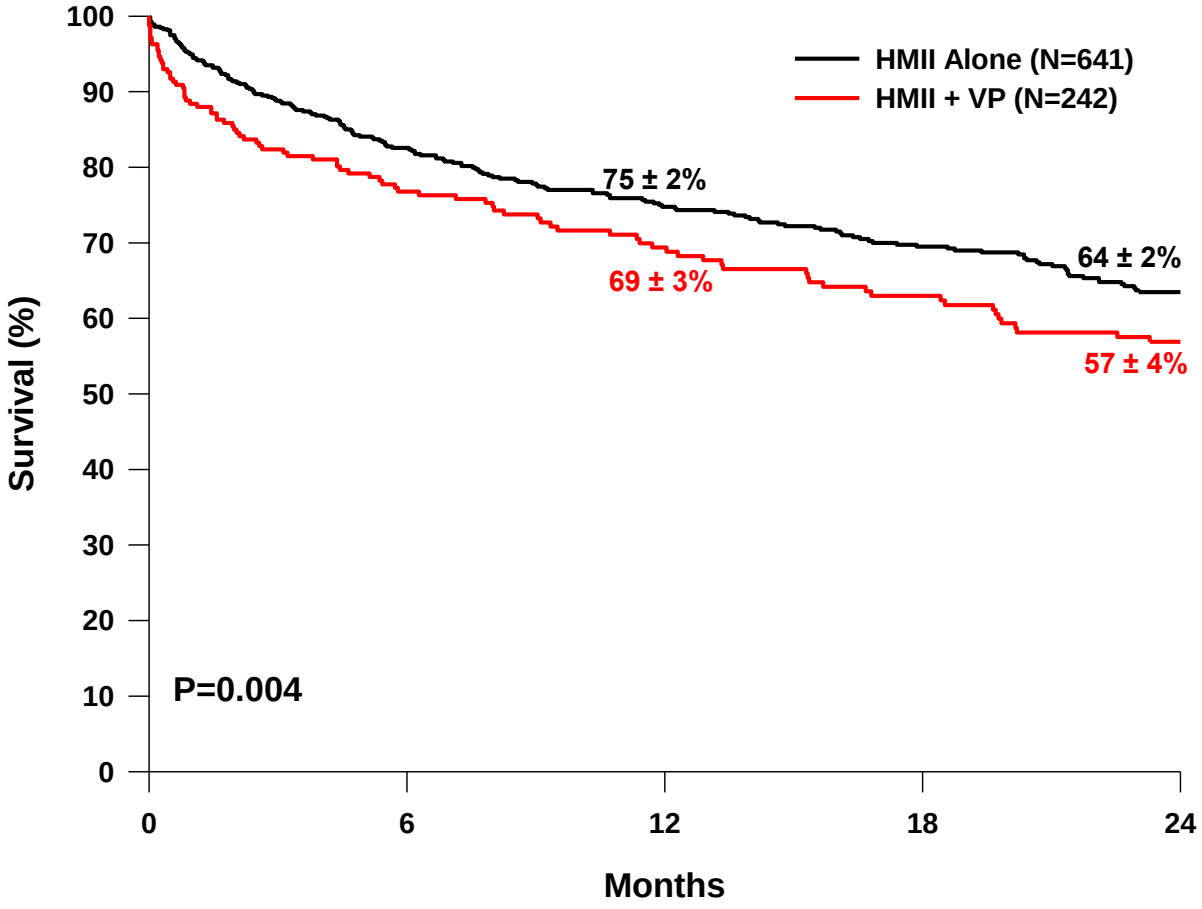
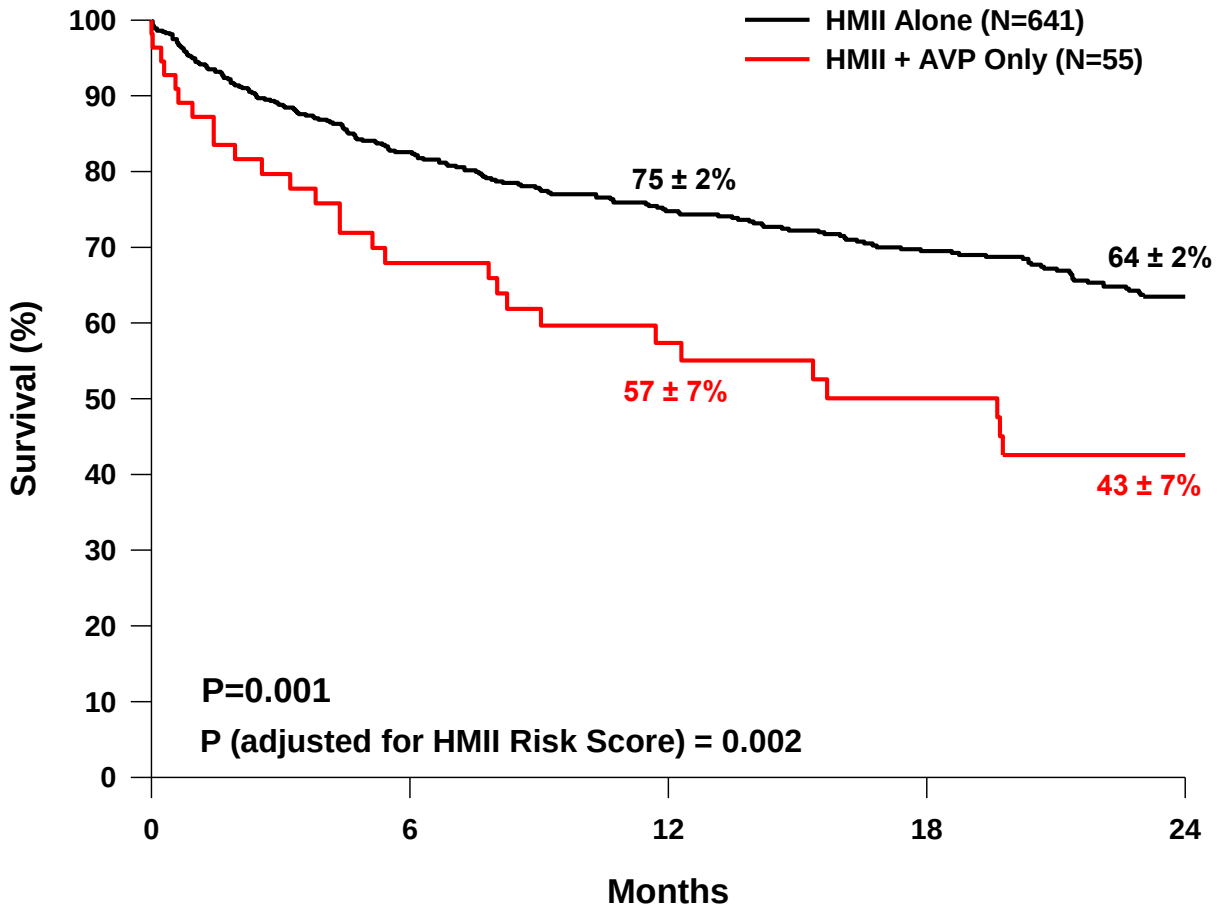
Aortic Procedures: Outcomes

Patients	N	30-day Mortality
Aortic Valve Closure	32	2 (6.3%)
Aortic Valve Repair	18	3 (18%)
AV Replacement	30	4 (13%)
Total	**80**	**9 (11.3%)**

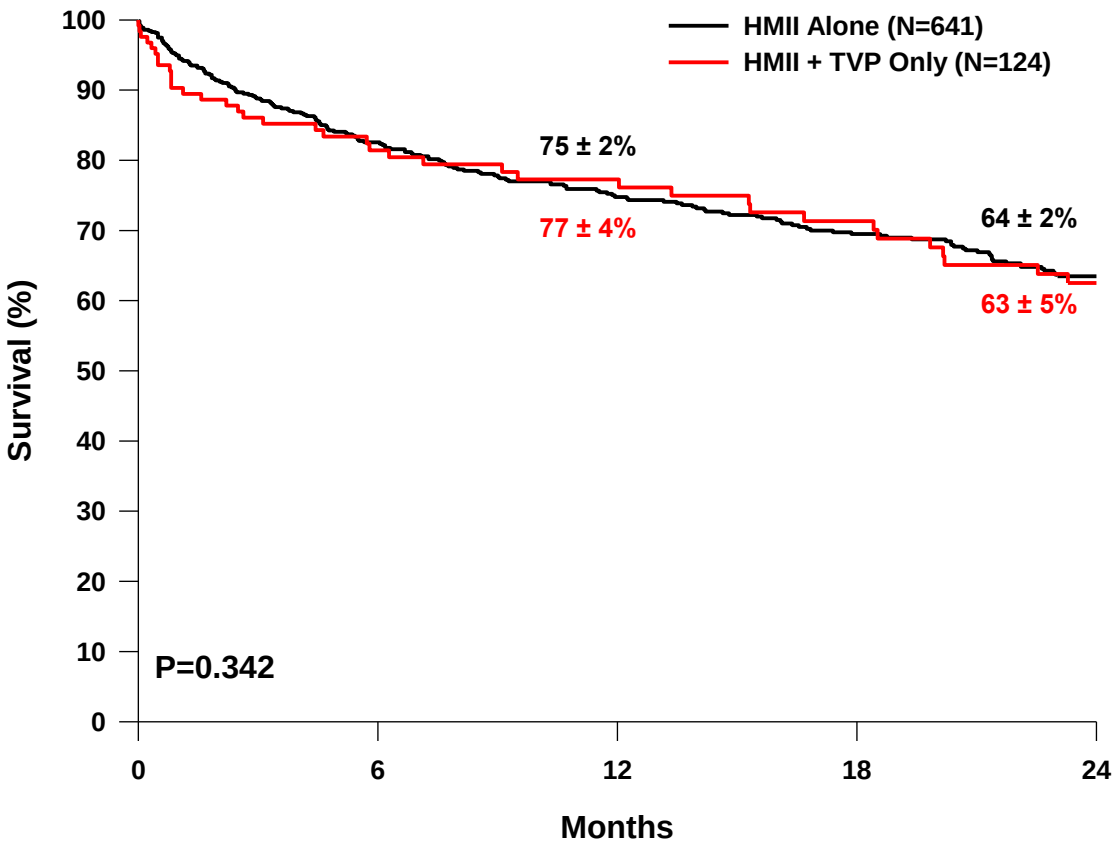
Survival: LVAD Alone vs. LVAD + VP



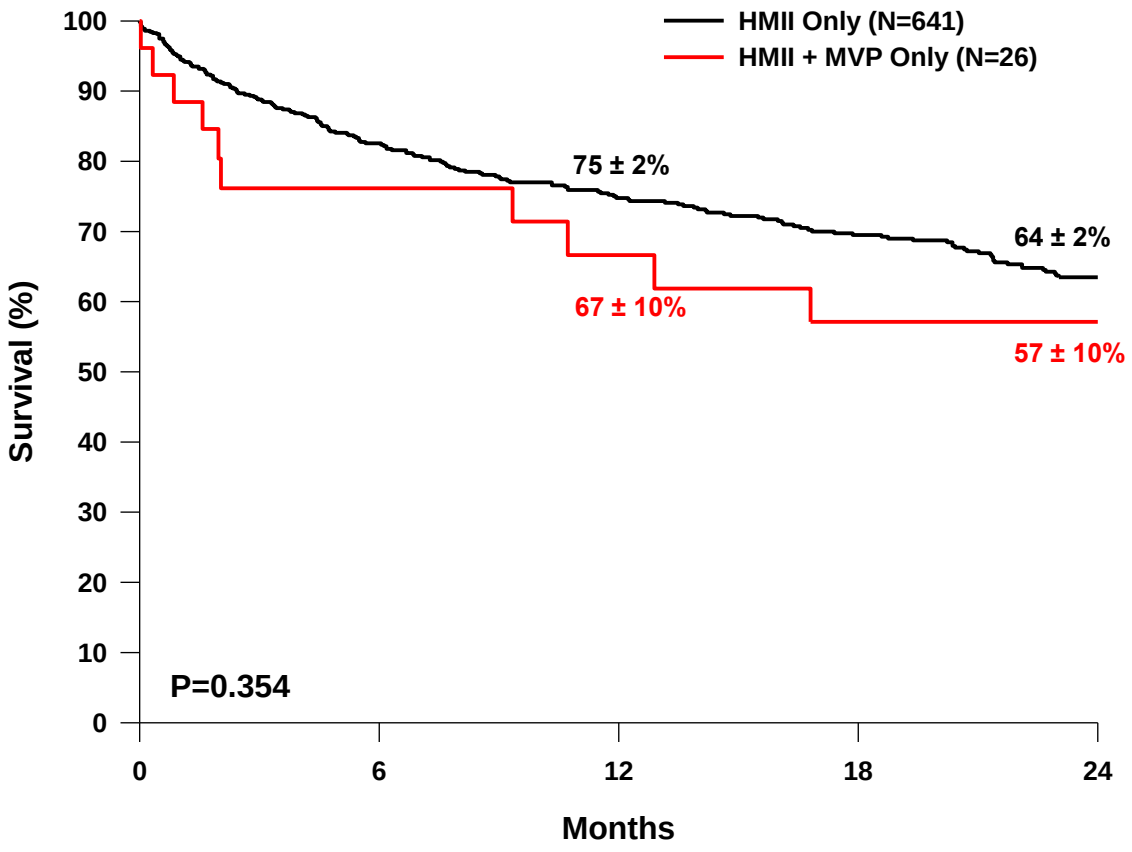
Survival: LVAD Alone vs. LVAD + AVP Only



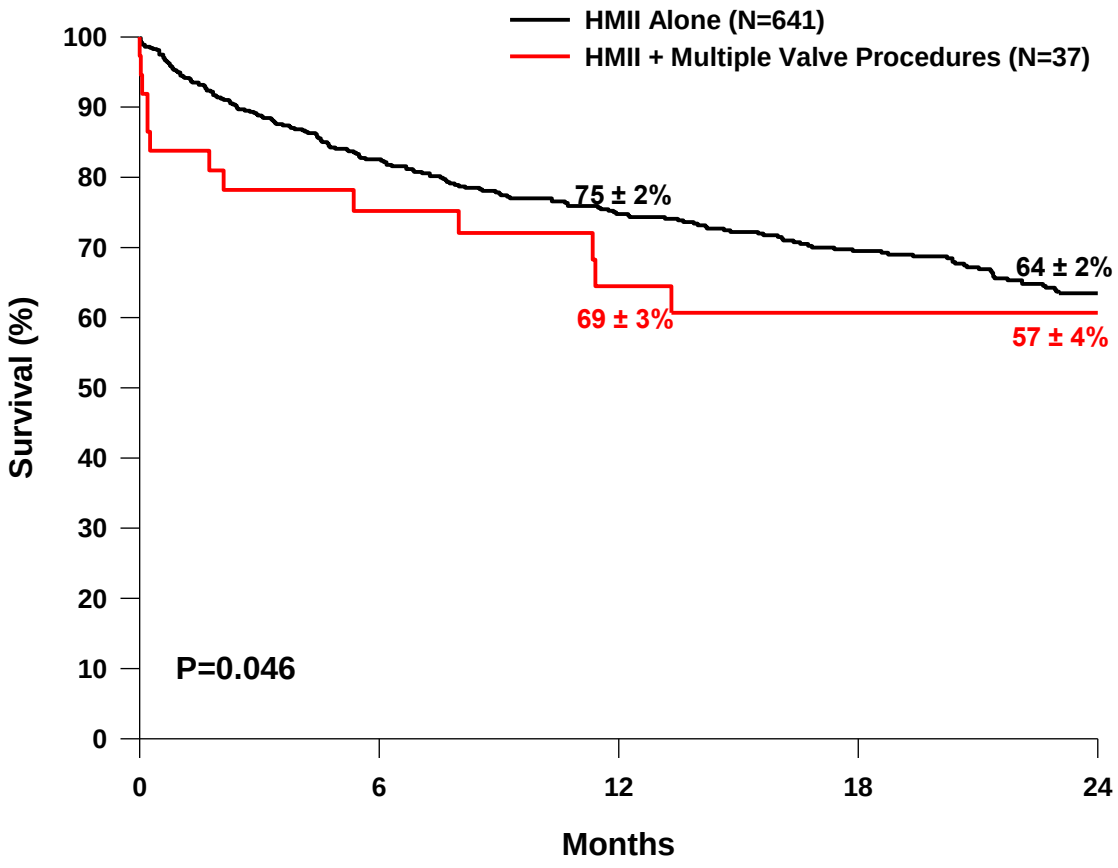
Survival: LVAD Alone vs. LVAD + TVP Only



Survival: LVAD Alone vs. LVAD + MVP Only



Survival: LVAD Alone vs. LVAD + Multiple Valve Procedures



Adverse Events in the first 30 days

Adverse Event	HMII Alone (n=641)	HMII + Valvular Procedures (n=242)	p-value
Bleeding < 30 days	311 (49%)	126 (52%)	0.366
Bleeding requiring surgery < 30 days	108 (17%)	46 (19%)	0.487
Right Heart Failure < 30 days	85 (13%)	48 (20%)	0.02
RVAD < 30 days	9 (1.4%)	22 (9.1%)	< 0.001
Renal Dysfunction/Failure < 30 days	36 (6%)	20 (8%)	0.164
Ischemic Stroke < 30 days	15 (2.3%)	4 (1.7%)	0.614
Hemorrhagic Stroke < 30 days	8 (1.3%)	2 (0.8%)	0.736

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Summary – AORTIC VALVE

- Patients have a higher HM II risk score (mainly due to older age)
- **Survival is worse** compared to HM II alone group, predominantly driven by higher early mortality
- No difference in adverse events
- Difference in survival between HM II alone and HM II plus valve procedures is driven by aortic valve procedures

Summary – TRICUSPID VALVE

- These patients have all the **signs of RV failure preoperatively** – higher CVP, higher CVP/PCWP ratio, lower right ventricular stroke work index (RVSWI), and higher BUN

- **No difference in survival** with a tricuspid valve procedure being performed

- **Higher risk of post operative right heart failure** in these patients

LIMITATIONS

- Non randomized study with no real risk-adjusted group for direct comparison
- Important variables not examined; e.g., baseline echo data
- Decision making of when to intervene (and how to) were left to individual decision making

CONCLUSIONS

- Patients frequently require concurrent valvular procedures at time of LVAD implant (20%)
- Higher mortality is seen in patients undergoing concurrent aortic valve procedures
- Despite a sicker group, patients undergoing tricuspid valve procedures have similar survival to HM II alone