

Device INTERMACS Database

June 5th, 2020

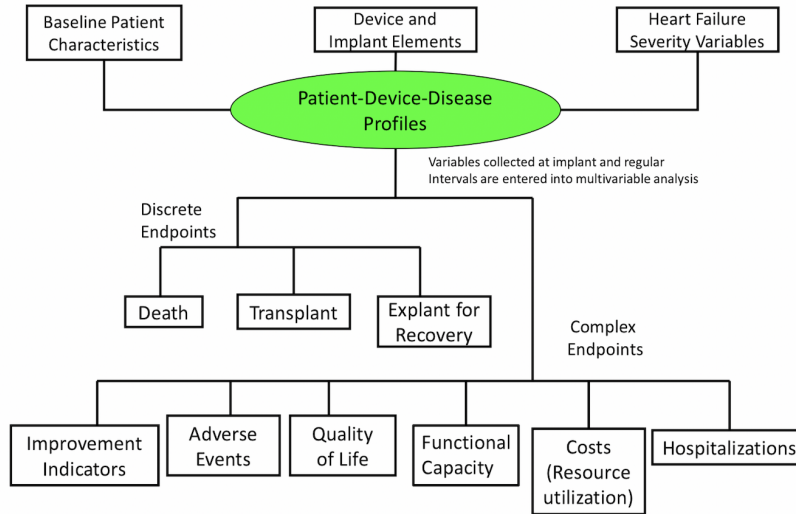
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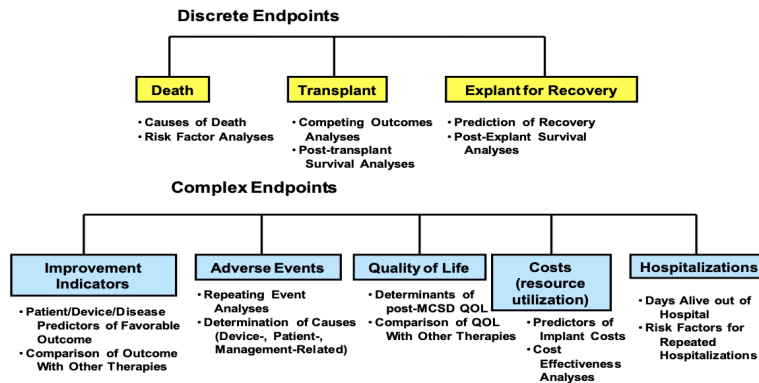
1 Device ID table

Trial	Device	Sponsor	CTID	Start Date	End Date	Size	Single Arm	Control Arm	Control Size
HM3_a	HeartMate 3	Abbott Medical Devices	NCT02170363	Jun 2014	Nov 2014	50	yes	none	0
HM3_b	HeartMate 3	Abbott Medical Devices	NCT02170363	Jun 2014	Nov 2014	50	yes	none	0
HM2P	HeartMate 2	Thoratec	NCT00121472	Mar 2005	May 2006	133	yes	none	0
HM2BTT	HeartMate 2	Thoratec	NCT00121472	Mar 2005	Nov 2006	196	yes	none	0
HVADCE	HeartWare HVAD	HeartWare		Mar 2006	Nov 2007	23	yes	none	0
HVADBTT	HeartWare HVAD	HeartWare	NCT00751972	Aug 2008	Aug 2010	140	no	INTERMACS	499
VELVAS	HeartMate VE	Thoratec		Feb 1996	Sep 1998	280	no	HeartMate IP	48
N100PC	Novacor N100 PC	Novacor Corp		Nov 1993	Oct 1996	118	yes	none	0
NovacorN100	Novacor N100 PCq	Novacor Corp		Oct 1997		19	yes	none	0
ThoratecIVAD_a	Thoratec IVAD	Thoratec		Jan 2002	Dec 2007	24	yes	none	0
ThoratecIVAD_b	Thoratec IVAD	Thoratec		Oct 2001	Jun 2004	39	no	Thoratec PVAD	100
ThoratecD	HeartMate XVE	Thoratec		Jan 2003	Dec 2004	42	no	HeartMate VE LVAD	68
HeartMateIP_a	HeartMate IP	Thermo Cardiosystems		May 1985	Feb 1991	34	no	historic control	6
HeartMateIP_b	HeartMate IP	Thermo Cardiosystems		Feb 1992	Apr 1993	12	yes	none	0
ThoratecPVAD	Thoratec PVAD	Thoratec		Sep 1996	Sep 2006	71	yes	none	0

Baseline Variables And Endpoints



Sample Endpoint Analyses



2.2 Figure References

- Protocol
 - A.5.4 Primary Endpoint (pp.19)
 - B.1.4 Major Endpoint (pp.29)
- MoP
 - 6.7 Data Collection (pp. 22-27)

3 Data Dictionary

3.1 Baseline Covariances

Dictionary	Number	Variable	Label
patients	941	AGE_DEIDENT	Age at Implant
patients	323	GENDER	Gender
patients	150	HGT_CM	Height (cm)
patients	153	WGT_KG	Weight (kg)
patients	329	RACE_WHITE	Race (White)
patients	327	RACE_AF_AMER	Race (Black)
patients	329	PRIMARY_DGN	Primary Diagnosis
patients	157	DEVICE_STRATEGY	Current Device Strategy/Indication
		BTT	Bridge to Transplant
		DT	Destination Therapy
patients	226	PX_PROFILE	Patient Profile at Time of Implant
patients	596	HR_RATE	Heart Rate
patients	598	SYS_BP	Systolic Blood Pressure (mmHg)
patients	600	DIA_BP	Diastolic Blood Pressure (mmHg)
patients	612	PUL_SYS_PRES	Pulmonary Artery Systolic Pressure (mmHg)
patients	614	PUL_DIA_PRES	Pulmonary Artery Diastolic Pressure (mmHg)
patients	608	LVEF	Left Ventricular Ejection Fraction
patients	616	RA_PRES	Mean RA Pressure (mmHg)
patients	618	PUL_WEDGE_PRES	Pulmonary Artery Wedge Pressure (mmHg)
patients	507	BUN_MG_DL	Bun (mg/dL)
patients	510	CREAT_MG_DL	Creatinine (mg/dL)
patients	513	BILI_TOTAL_MG_DL	Total Bilirubin (mg/dL)
patients	523	SODIUM_MMOL_L	Sodium (mmol/L)
patients	525	INR	International Normalized Ratio
patients	527	WBC_X10_3_UL	White Blood Cell Count (x10/uL)
patients	530	PLATELET_X10_3_UL	Platelet (x10/uL)
patients	533	SGOT_AST	Aspartate Aminotransferase/AST (u/L)
patients	535	SGPT_ALT	Alanine Aminotransferase/ALT (u/L)
patients	537	CHOLESTEROL_MG_DL	Total Cholesterol (mg/dL)
patients	542	POTASSIUM_MEQ_L	Potassium (mEq/L)
patients	545	HEMOGLOBIN_G_DL	Hemoglobin (g/dL)
patients	573	ALBUMIN_G_DL	Albumin (g/dL)
patients	576	BNP_PG_ML	Brain Natriuretic Peptide (pg/mL)
patients	487	MED_PRE_IMP_ACE_INHIBITORS	ACE Inhibitors
patients	488	MED_PRE_IMP_BETA_BLOCKERS	Beta Blockers
patients	201	IV_INO_THERAPY	IV Inotrope Therapy
		ISCHEMIC	Ischemic Etiology
followup	198	CARDIAC_INDEX	Cardiac Index

3.2 Endpoints/Outcomes

Dictionary	Number	Variable	Label
events	310	EVENTX	Adverse Event Type
events	311	INT_EVT	Event Interval (mths)
patients	476	DEAD	Dead Indicator
patients	440	TIMING_DEATH	Time of Death
patients	480	INT_DEAD	Interval from implant to death (mths)
events	197	PRIM_ADMIS_RSN	Primary Rehospitalization Reason
		MACE	Major Adverse Cardiovascular Events
		RHF	Right Heart Failure
		myocardial	myocardial infarction
		ischemic_stroke	ischemic stroke
		hemorrhagic_stroke	hemorrhagic stroke

3.3 Device Type

Dictionary	Number	Variable	Label
device	340	DEVICE_TY	Device Type
		LVAD	Left Ventricular Assist Device
		RVAD	Right Ventricular Assist Device
		BiVAD	LVAD+RVAD in same or visit
		TAH	Total Artificial Heart

4 Notes

4.1 Follow-up Form_ID

Follow-up Interval	Form_ID
1 week	12
1 month	13
3 months	14
6 months	15
12 months	16
18 months	17
24 months	18

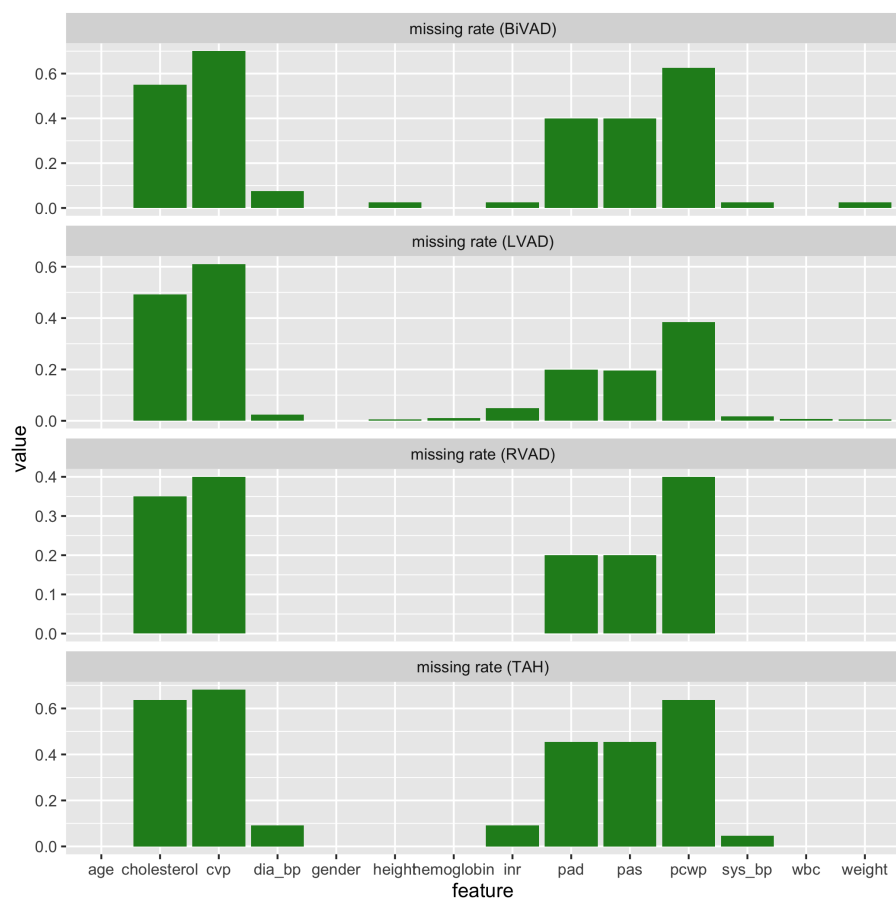
4.2 Relevant Publications/Reports

- [INTERMACS_Publications](#)
- [Low_Accuracy_of_the_HeartMate_Risk_Score](#)
- [Results of the Post-FDA-Approval Study with HM2 Using the INTERMACS](#)

4.3 Notes collected from INTERMACS Database

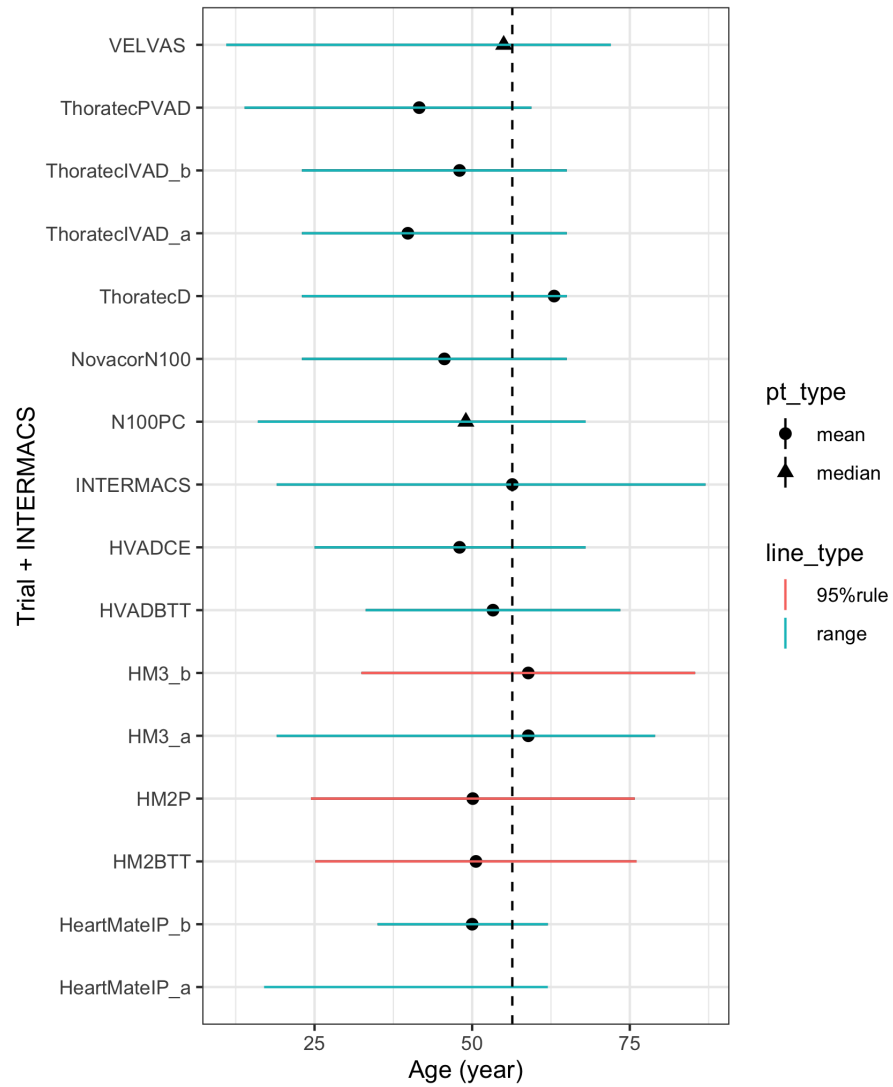
- Lack of DEVICE_BRAND
- CHOLESTEROL only in followup.csv
- EVENTX in event.csv contains all the possible adverse events such as bleeding, dev mal, re hosp.
- PATIENT_REPORT_ID: one-to-one correspondence to each occurrence of adverse event(s).
- A patient has two or more OPER_ID if and only if the corresponding EVENTX contains “Explant: Exchange” or “Explant: Transplant.”

5 Baseline Missing Rate

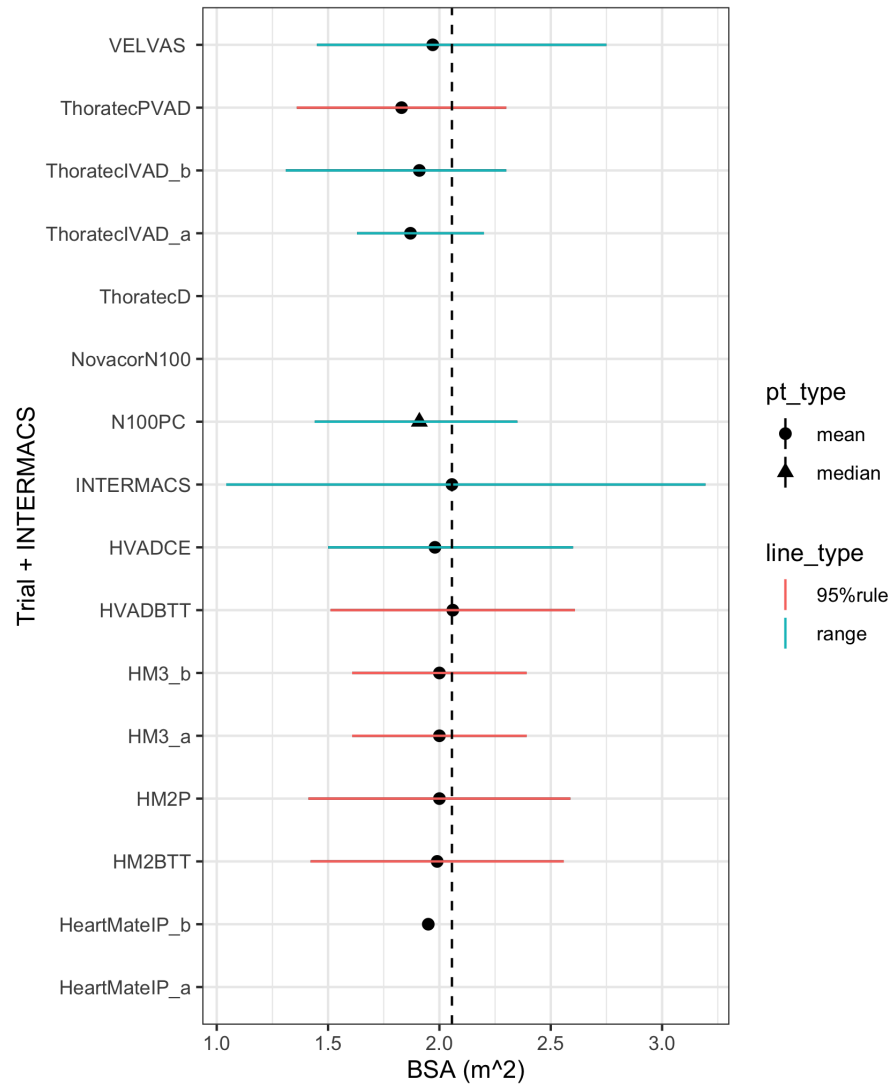


6 Continuous Baseline Forest Plot

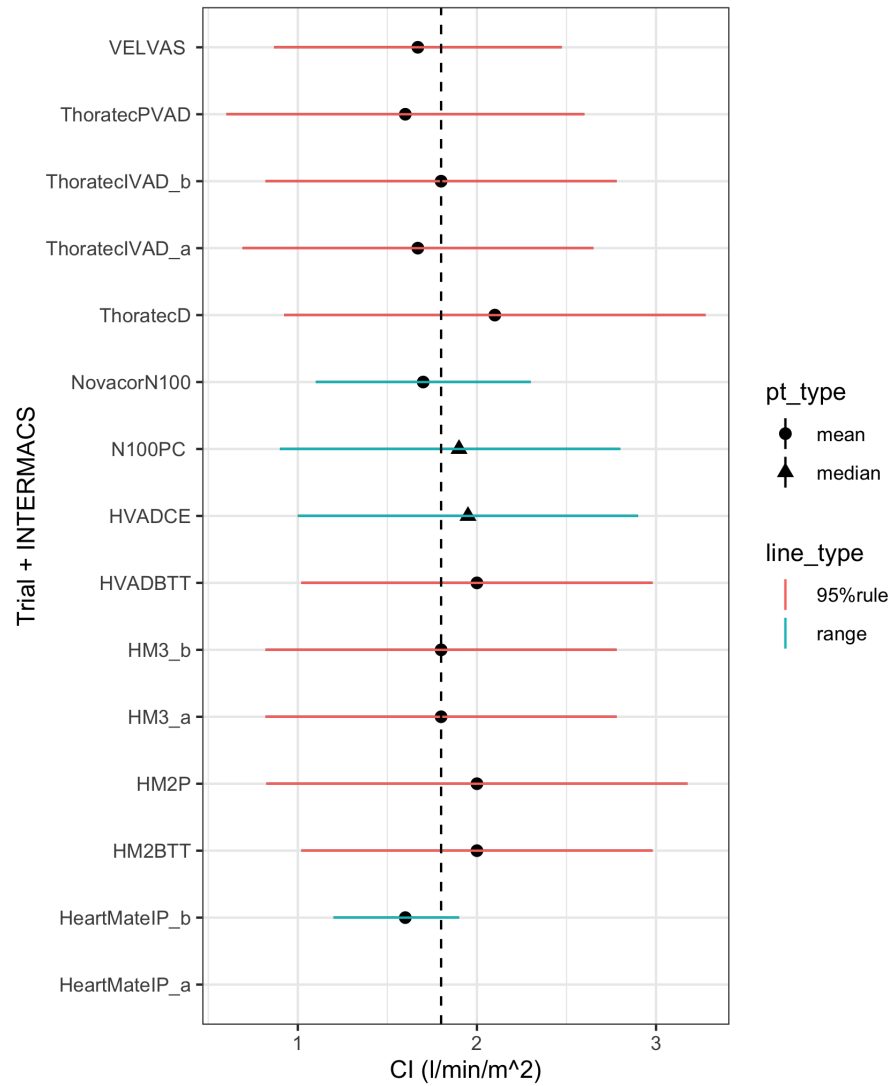
6.1 Age (includes INTERMACS)



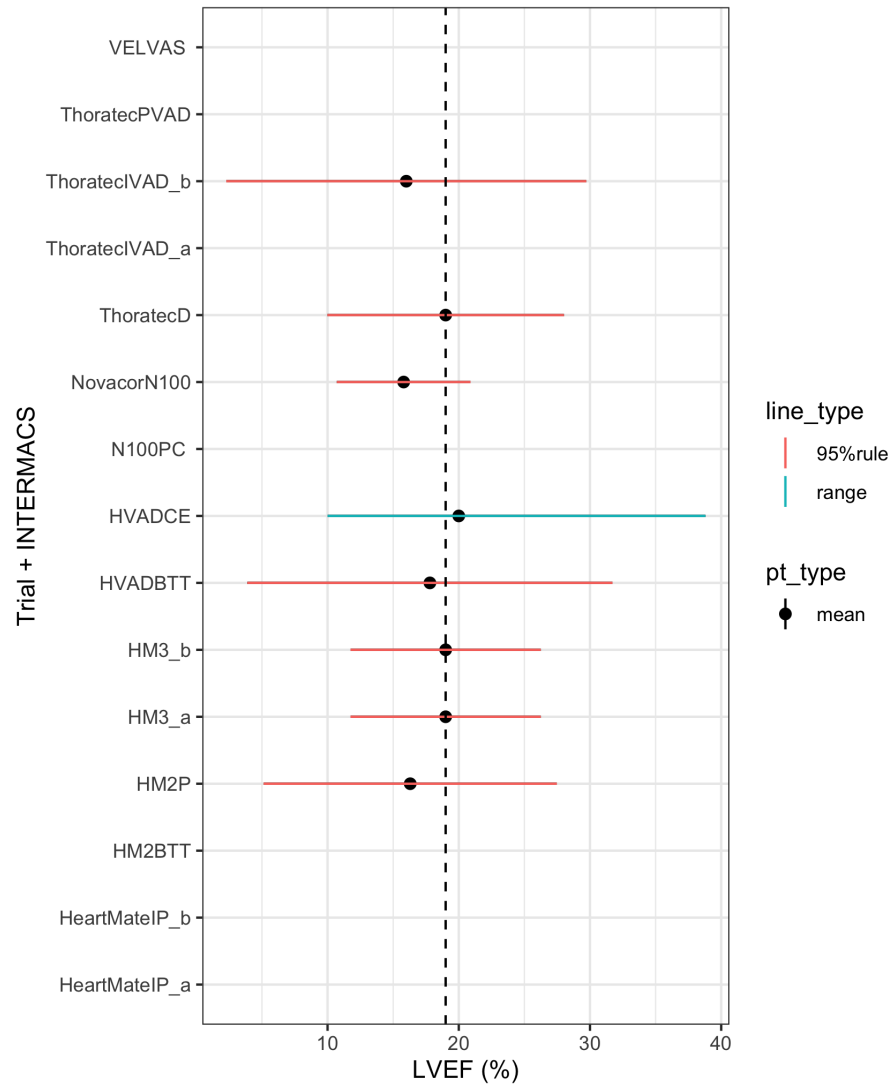
6.2 BSA (includes INTERMACS)



6.3 CI

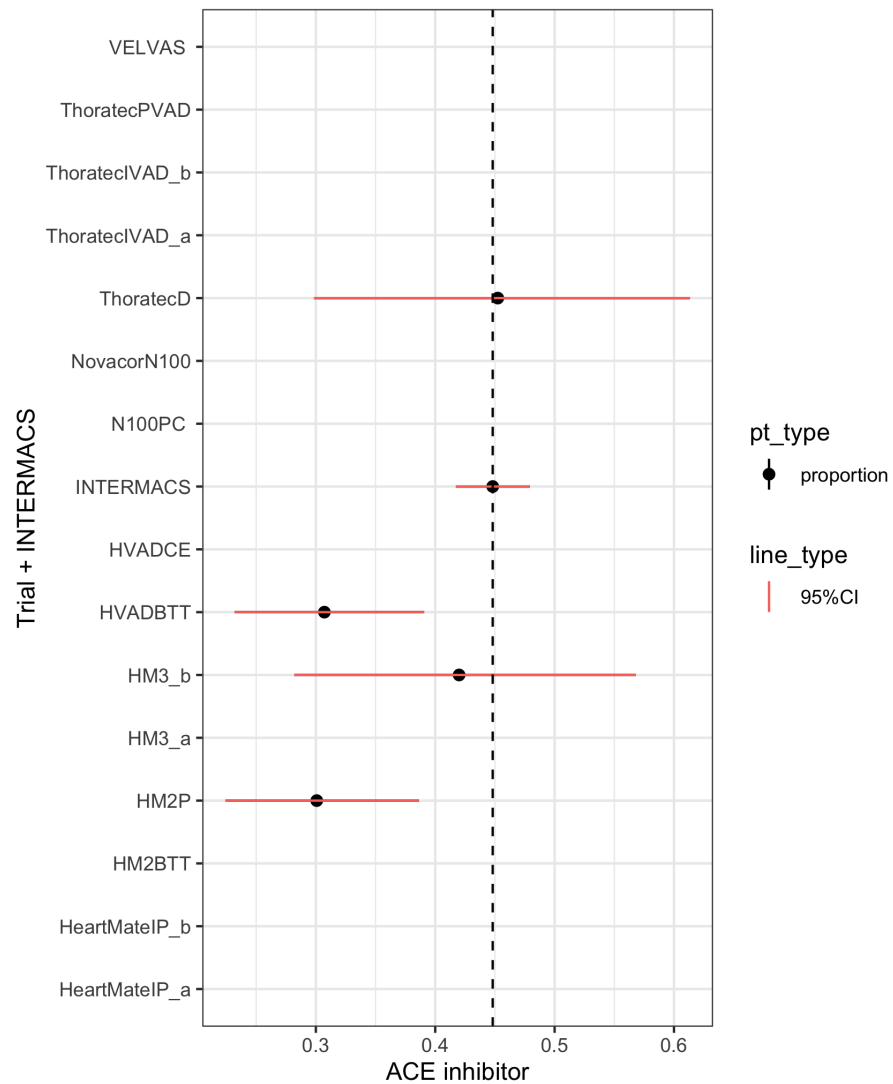


6.4 LVEF

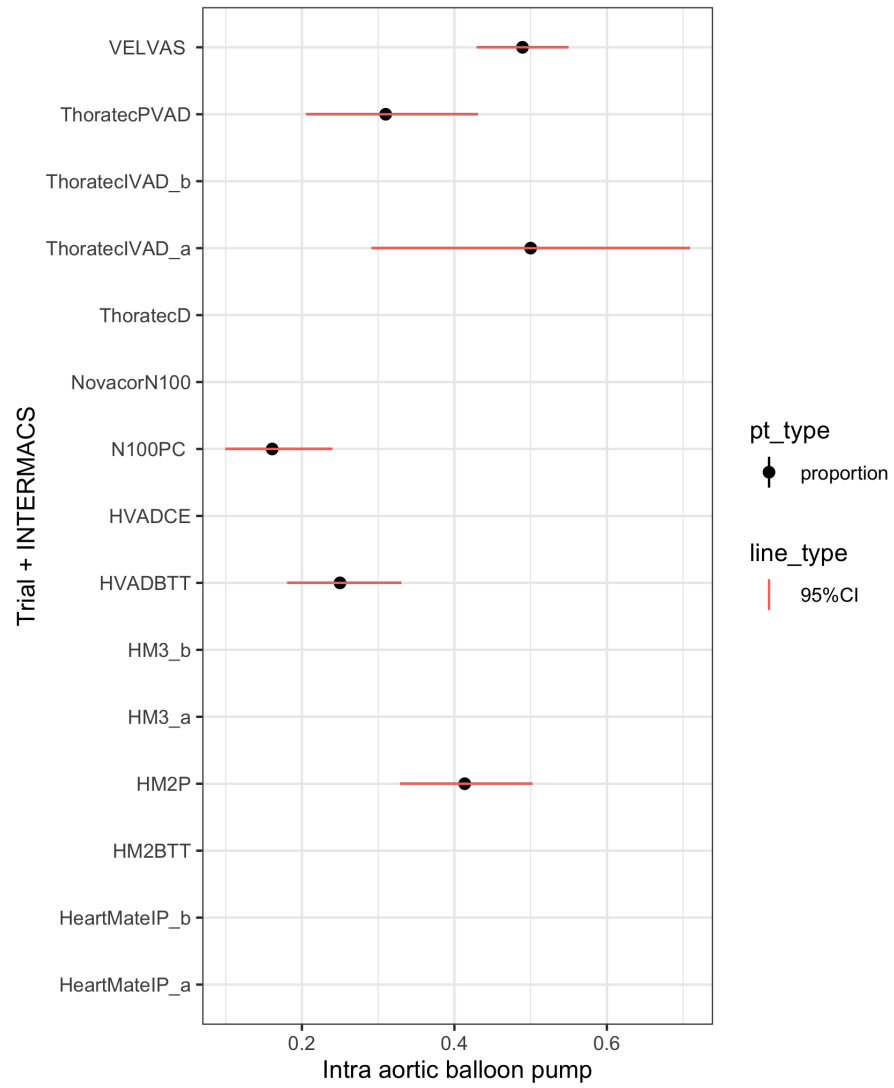


7 Categorical Baseline Forest Plot

7.1 ACE inhibitor (includes INTERMACS)



7.2 IABP



7.3 Ischemic cardiomyopathy (includes INTERMACS)

