

**Insufficienza cardiaca avanzata:
ripensare accesso, decisioni e percorsi clinici**

Registro ITAMACS: Un'esperienza tutta italiana

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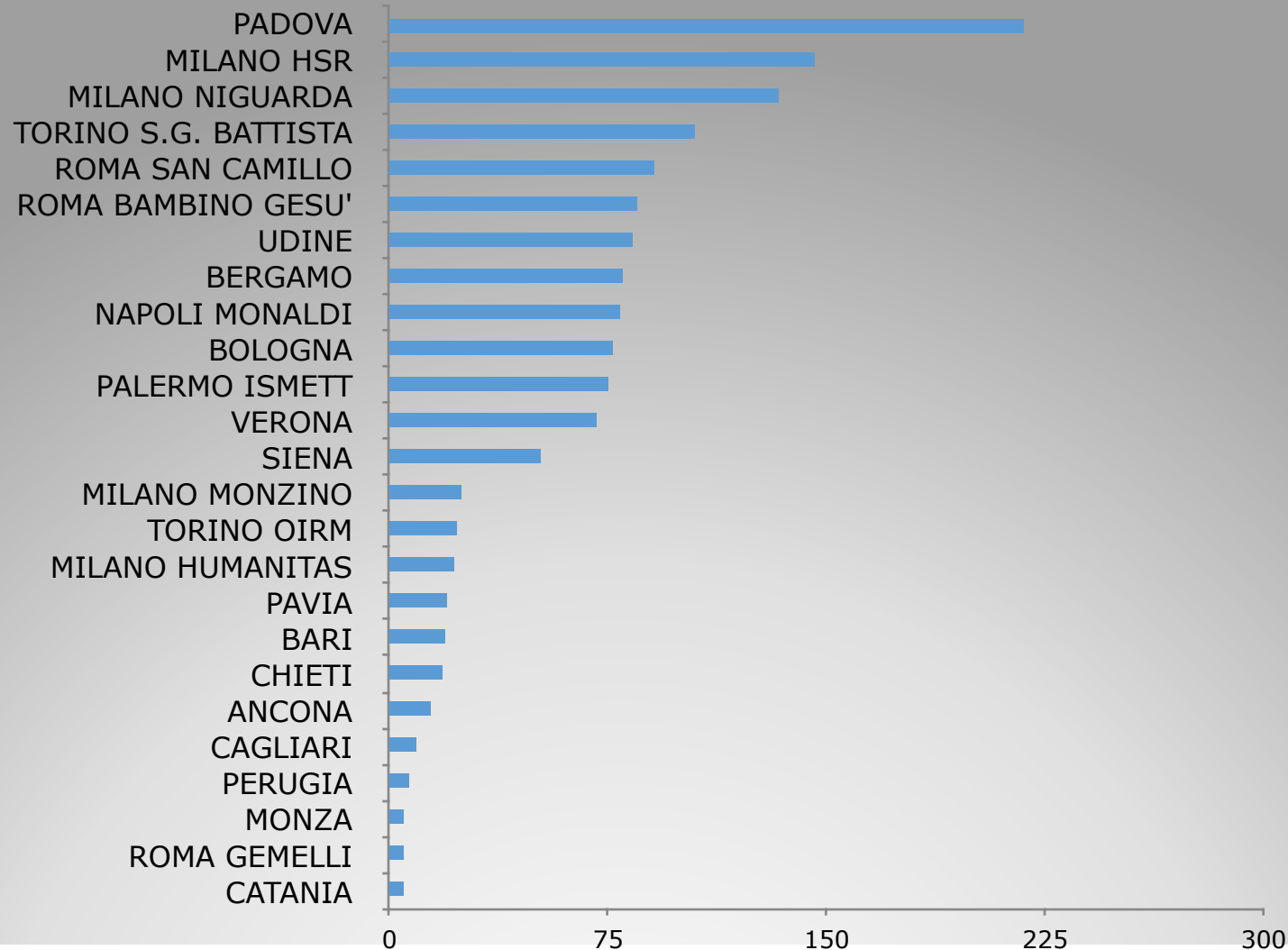




CENTRO

PADOVA	218
MILANO HSR	146
MILANO NIGUARDA	134
TORINO S.G. BATTISTA	105
ROMA SAN CAMILLO	91
ROMA BAMBINO GESU'	85
UDINE	84
BERGAMO	80
NAPOLI MONALDI	79
BOLOGNA	77
PALERMO	75
VERONA	71
SIENA	52
MILANO MONZINO	25
TORINO OIRM	23
MILANO HUMANITAS	22
PAVIA	20
CHIETI	18
BARI	19
ANCONA	14
CAGLIARI	9
PERUGIA	7
MONZA	5
CATANIA	5
ROMA GEMELLI	5
Totale	1469

IMPIANTI VAD PER CENTRO



**Dati
(2010-2021)**

INTERMACS Registry

- Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)
- Funded by the United States National Heart, Lung and Blood Institute (NHLBI)
- Registry for patients who receive durable circulatory support devices (started 2005)
- First report: 2008

Last INTERMACS Report (16TH)

QUALITY REPORT

The Society of Thoracic Surgeons Intermacs 2025 Annual Report: Focus on Outcomes in Older Adults



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Thomas C. Hanff, MD, MSCE,⁴ Marisa Cevasco, MD, MPH,⁵ Jeffrey Keenan, MD,⁶
Michael Zhen-Yu Tong, MD, MBA,⁷ Arman Kilic, MD,⁸ Devin Koehl, MSDS,⁹
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30,072 patients

(Ann Thorac Surg 2026;121:15-40)

A

Primary Prospective Patients
Intermacs: January 1, 2015 – December 31, 2024
N=30,072

All Adult Durable CF
Isolated LVAD
N=28,029

Historical Non-Mag-Lev
2015-2017
N=8,110

Non-Mag-Lev
2018-2024
N=3,112

Mag-Lev
2018-2024
N=16,797

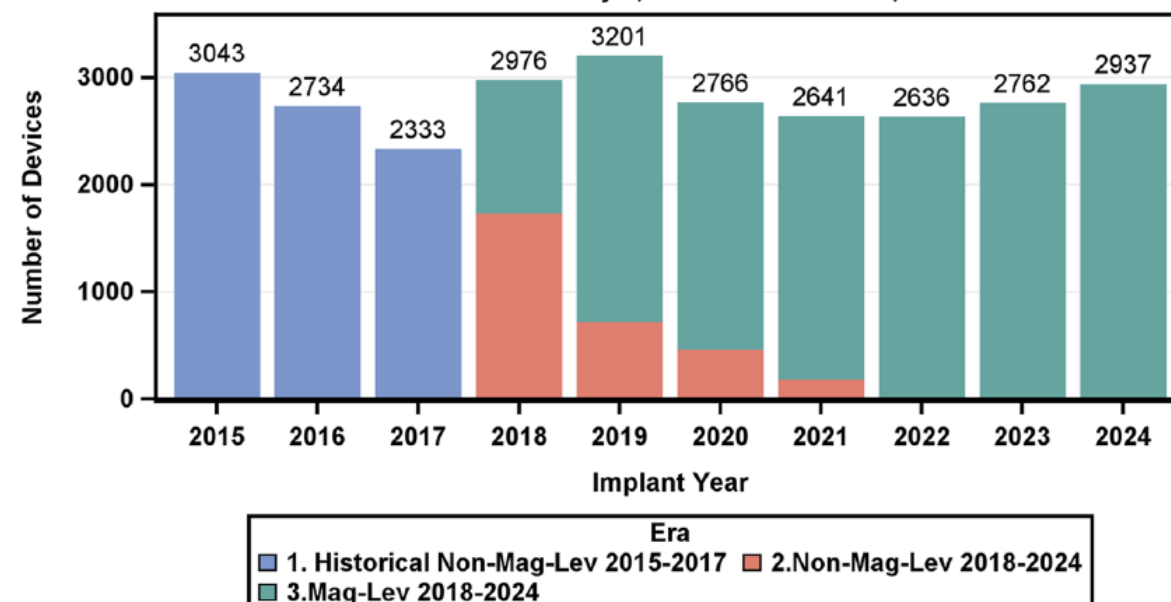
Exclude:	n
Isolated PF RVAD	1
Isolated CF RVAD	15
TAH	265
Isolated PF LVAD	6
PF BiVAD	14
CF BiVAD	1742
Total	2043

PF = pulsatile flow pump
CF = continuous flow pump
RVAD: right ventricular assist device
LVAD: left ventricular assist device
TAH: total artificial heart
BiVAD: biventricular assist device

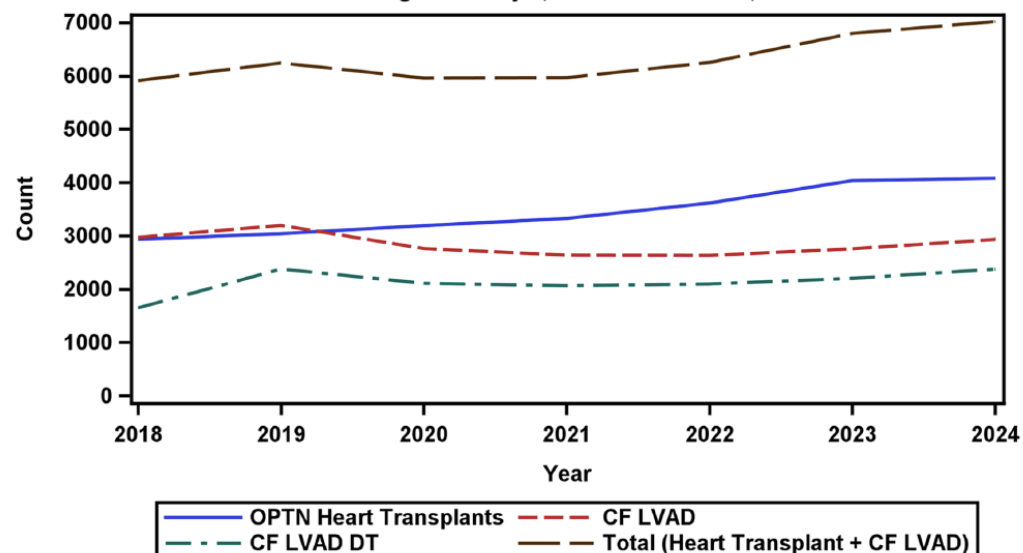
(Ann Thorac Surg 2026;121:15-40)

B

Primary CF LVAD Implants by Year
Intermacs: January 1, 2015 - December 31, 2024

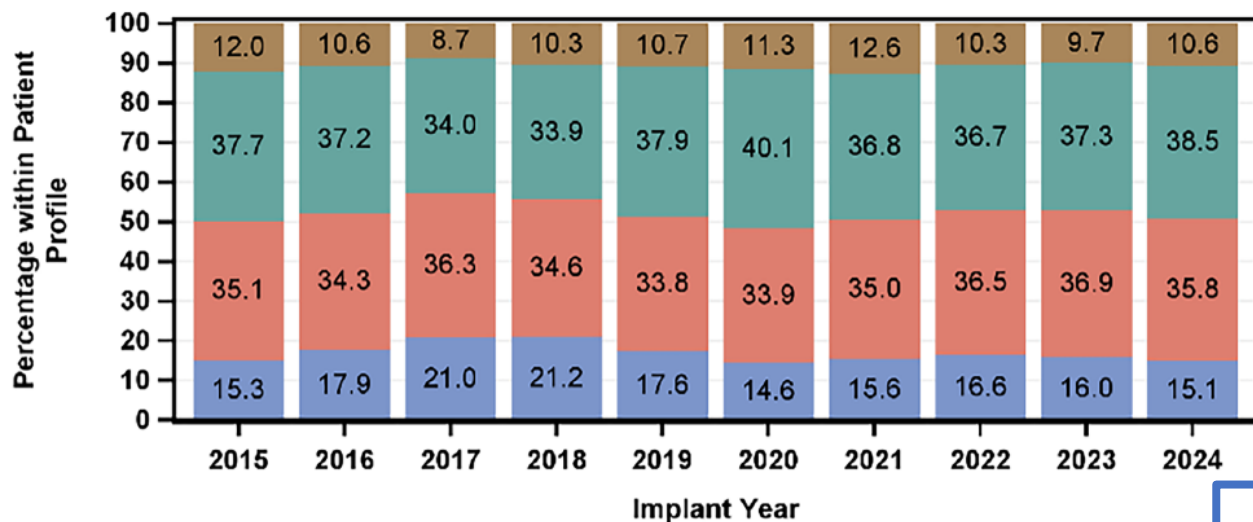


Heart Transplant and CF LVAD Counts
Coverage: January 1, 2018-December 31, 2024



C

Patient Profile for Primary CF LVAD
Intermacs: January 1, 2015 - December 31, 2024



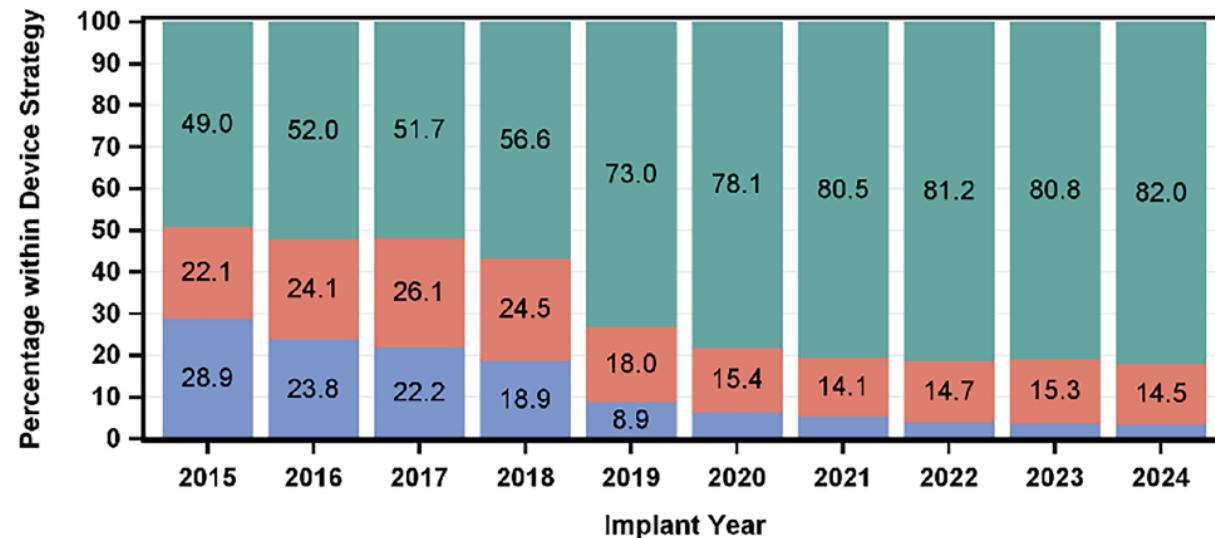
Patient Profile

- 1. Critical Cardiogenic Shock
- 2. Progressive Decline
- 3. Stable but Inotrope Dependent
- 4. Resting Symptoms

(Ann Thorac Surg 2026;121:15-40)

A

Device Strategy for Primary CF LVAD
Intermacs: January 1, 2015 - December 31, 2024



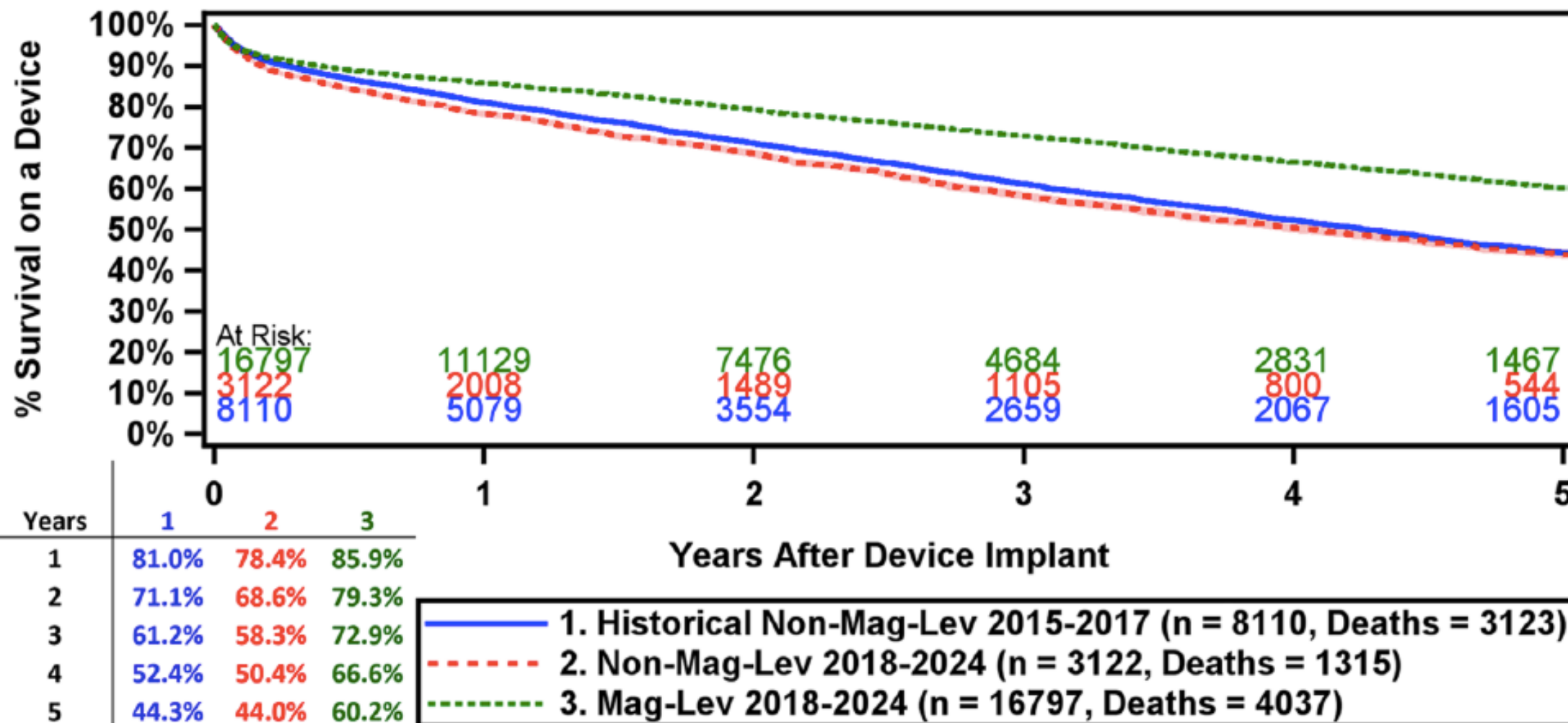
Device Strategy

- Bridge to Transplant - Listed
- Bridge to Candidacy
- Destination Therapy

(Ann Thorac Surg 2026;121:15-40)

Survival by Era and Device Type

Intermacros: January 1, 2015 - December 31, 2024



ITAMACS

Let's start from the beginning...

In **2013**, the Italian National Transplant Center (Centro Nazionale Trapianti, CNT, an agency of the Italian National Institute of Health) supported the development of the Italian multi-center registry for mechanically assisted circulatory support (ITAMACS)⁴. The CNT represents the regulatory and scientific organization responsible for the coordination of the solid organ transplant network across the Italian Regions. ITAMACS is a retrospective registry collecting data regarding durable ventricular assist device (VAD) and total artificial heart (TAH) implantations performed in Italy from 2010. All Italian centers performing durable MCS implantation regularly enter patient information in the ITAMACS database.

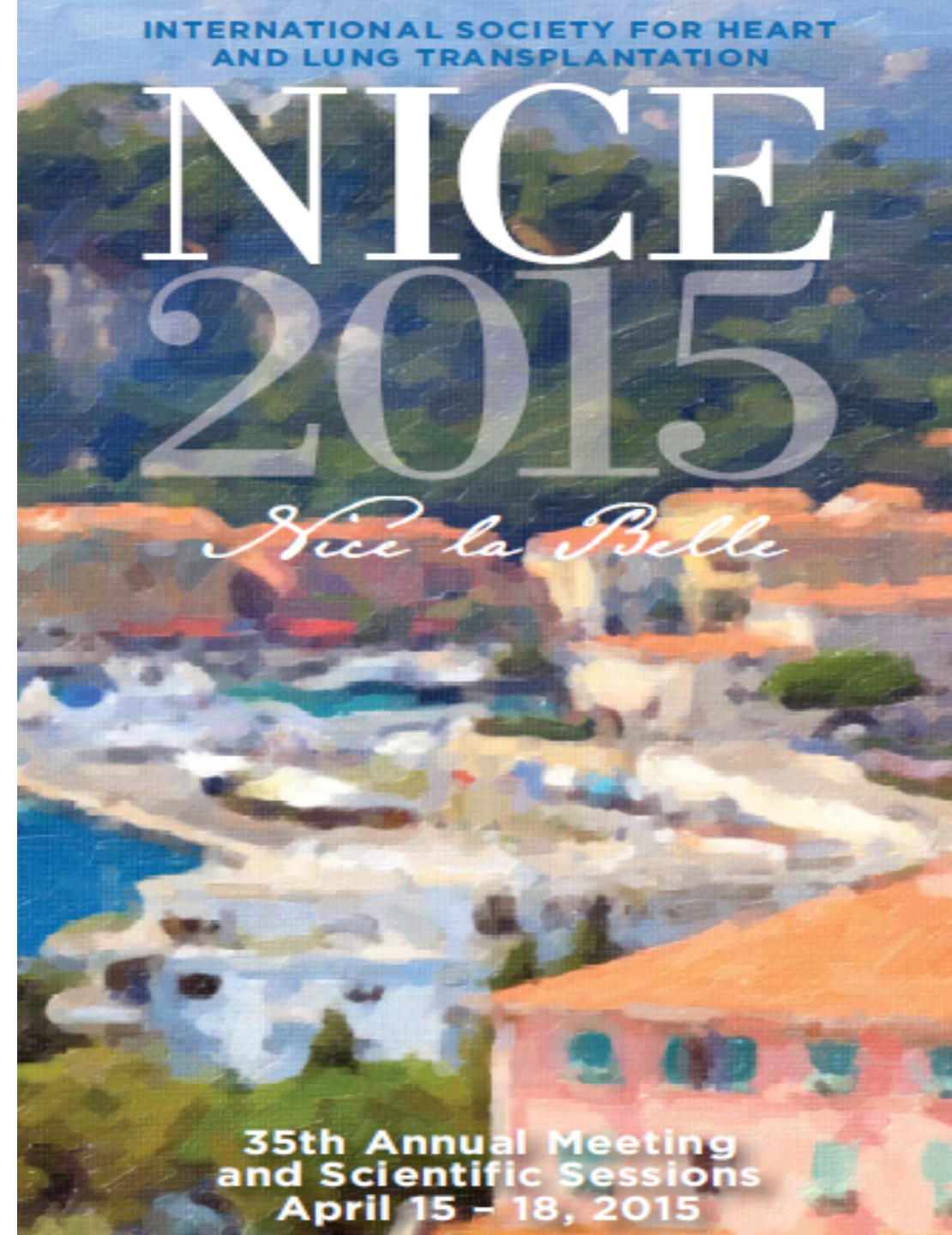
Preliminary Results From ITAMACS, the Italian Multi Center Registry for Mechanically Assisted Circulatory Support

Giuseppe Feltrin, MD, PhD

Regional Centre for Transplant Coordination

Regione Veneto, Italy

on behalf of the ITAMACS group





INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION
WASHINGTON DC
**36TH Annual Meeting
AND Scientific Sessions**
APRIL 27-30, 2016

***Destination Therapy in a single european country.
Insights from the ITAMACS registry***

Giuseppe Feltrin, MD, PhD

Regional Centre for Transplant Coordination

on behalf of the National Centre for

Transplant Coordination (Italian Ministry of Health) and the

ITAMACS group

The Italian Registry (Jan 2010 – Dec 2021)

Registry of Italian centers implanting d-MCS



Include all durable VAD implantation and TAH



Administered by the CNT



Data retrospectively collected and transmitted to a common database

HTx Centers

Bari
Bergamo
Bologna
Cagliari
Milano Niguarda
Napoli Monaldi
Padova
Palermo - ISMETT
Pavia
Roma Bambin Gesù
Roma San Camillo
Siena
Torino
Udine
Verona

Not HTx Centers

Ancona
Catania
Chieti
Milano Humanitas
Milano Monzino
Milano San Raffaele
Monza San Gerardo
Perugia
Roma Policlinico Gemelli
Torino Regina Margherita

25 Centers



Inclusion Criteria of Our Analysis:



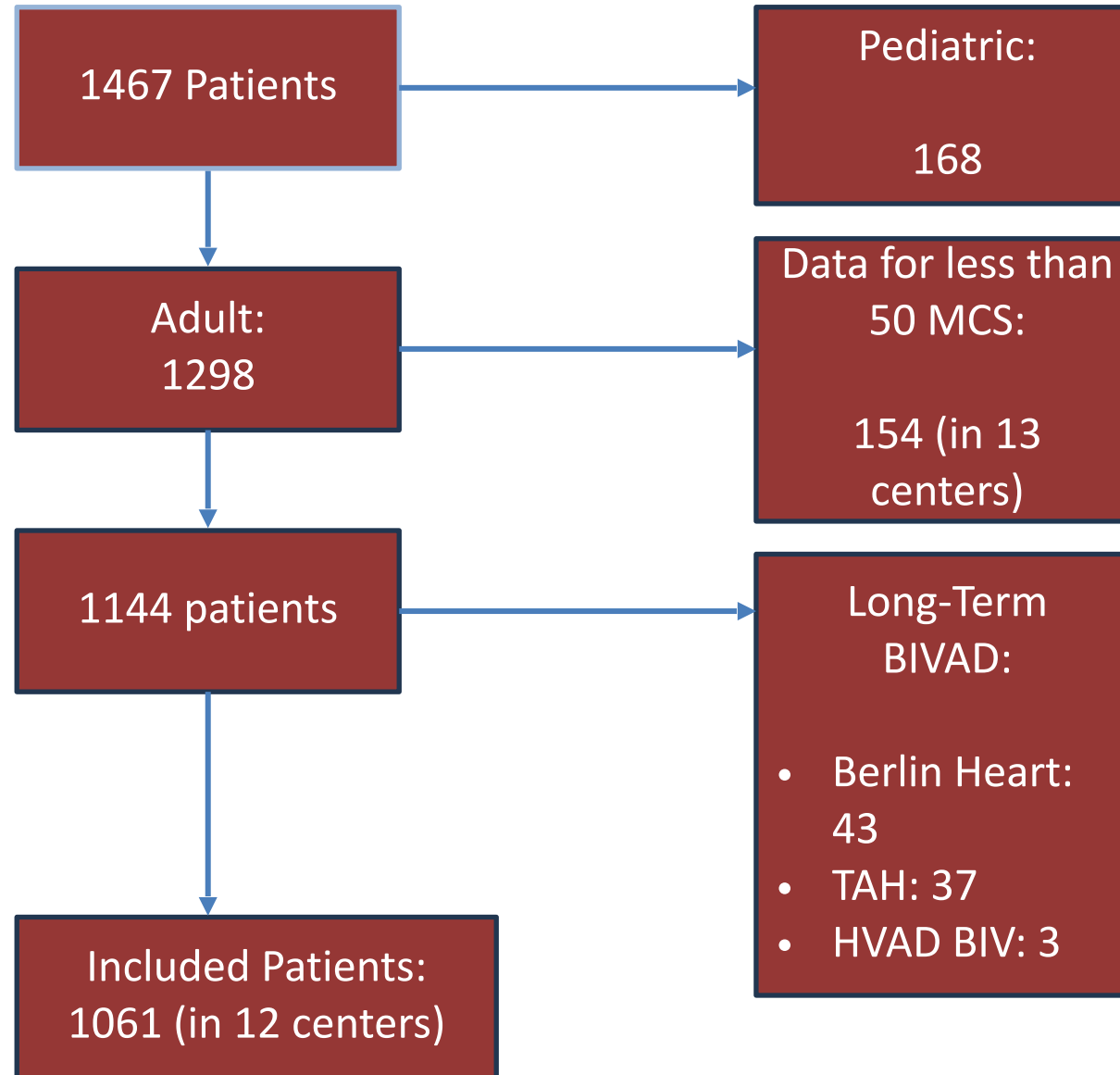
ADULT PATIENTS (>18)



INTRACORPOREAL LVAD



ONLY CENTER WITH DATA OF MORE
THAN 50 D-MCS IN THE ITAMACS
REGISTRY



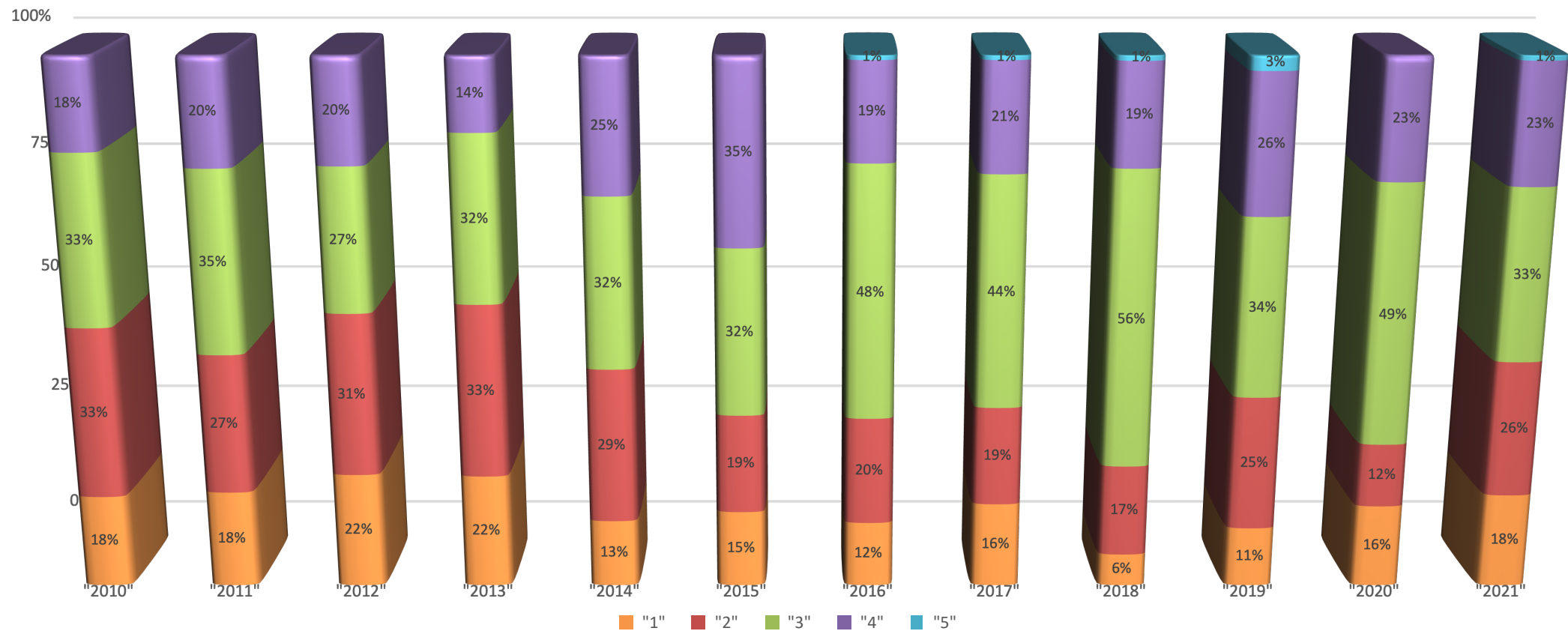
d-MCS per center

Center	Number of d-MCS implanted in Adults	Number of Isolated LVAD implanted in Adults	
	Patients	Patients	% of Total
PADOVA	203	193	18.2 %
MILANO SAN RAFFAELE	146	142	13.4 %
MILANO NIGUARDA	133	129	12.2 %
TORINO	105	97	9.1 %
ROMA SAN CAMILLO	90	87	8.2 %
PALERMO ISMETT	75	75	7.1 %
VERONA	71	71	6.7 %
UDINE	83	62	5.8 %
BERGAMO	65	58	5.5 %
BOLOGNA	57	57	5.4 %
SIENA	52	51	4.8 %
NAPOLI MONALDI	63	39	3.7 %

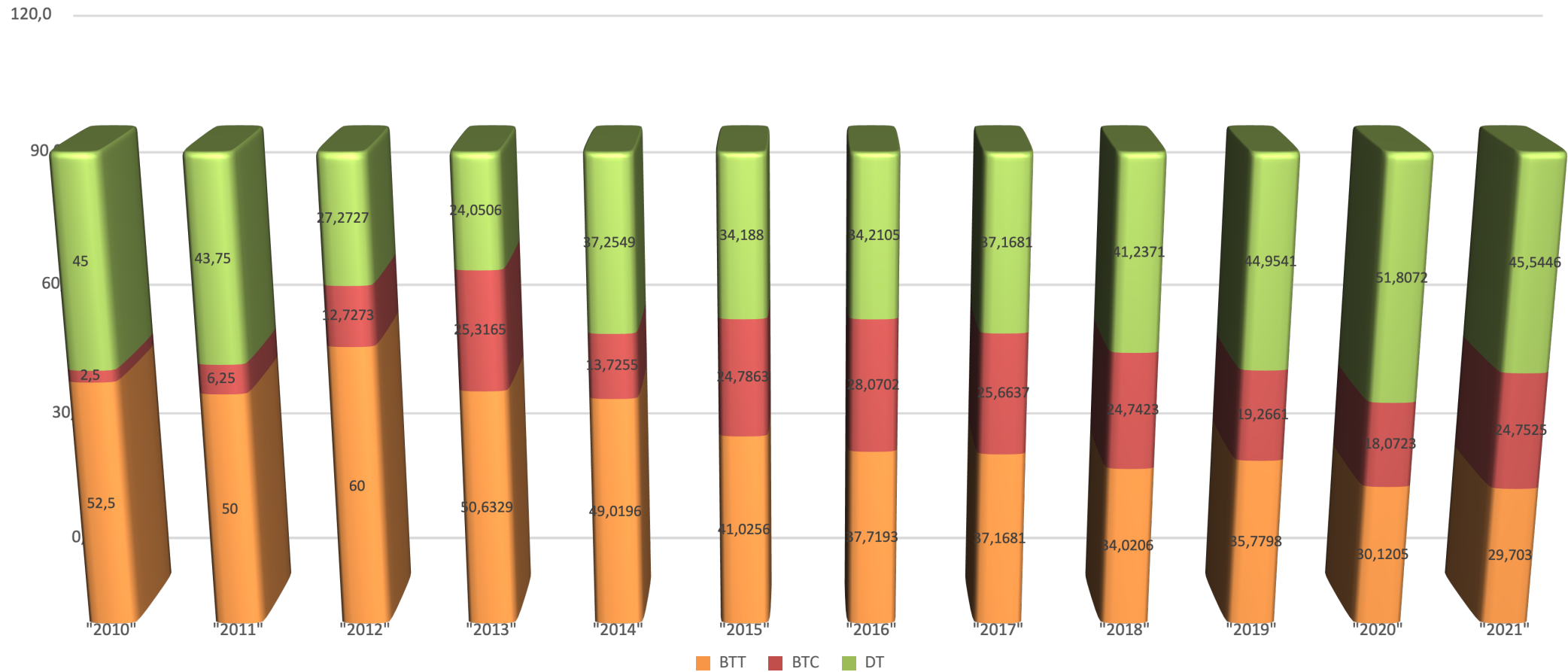
Baseline Characteristics

Age, median (IQR)	61 (54-66)	Diagnosis	
		Dilatative Secondary	605 (57.2%)
Female		Dilatative Primary	416 (39.3%)
	118 (11.1%)	Hypertrophic	16 (1.5%)
		Post-Myocarditis	14 (1.3%)
INTERMACS		GUCH	3 (0.3%)
1	156 (14.8%)	Restrictive	2 (0.2%)
2	245 (23.2%)	Arrhythmogenic	1 (0.1%)
3	408 (38.7%)	Post HTx	1 (0.1%)
4	239 (22.7%)		
5	7 (0.7%)	Indication	
		BTT	428 (40.5%)
Redo Surgery		DT	410 (38.8%)
	282 (36.2%)	BTC	220 (20.8%)

INTERMACS by year (%)



Indication by year (%)



Intra-Operative Characteristics

Device

HVAD	403 (38.0%)
HM3	363 (34.2%)
HM2	151 (14.2%)
JARVIK2000	141 (13.3%)
AVAD (Reliant Heart)	3 (0.3%)

Implant assisted

CPB	903 (85.4%)
ECMO	56 (5.3%)
Off-pump	98 (9.3%)

Temporary RVAD	27 (2.5%)
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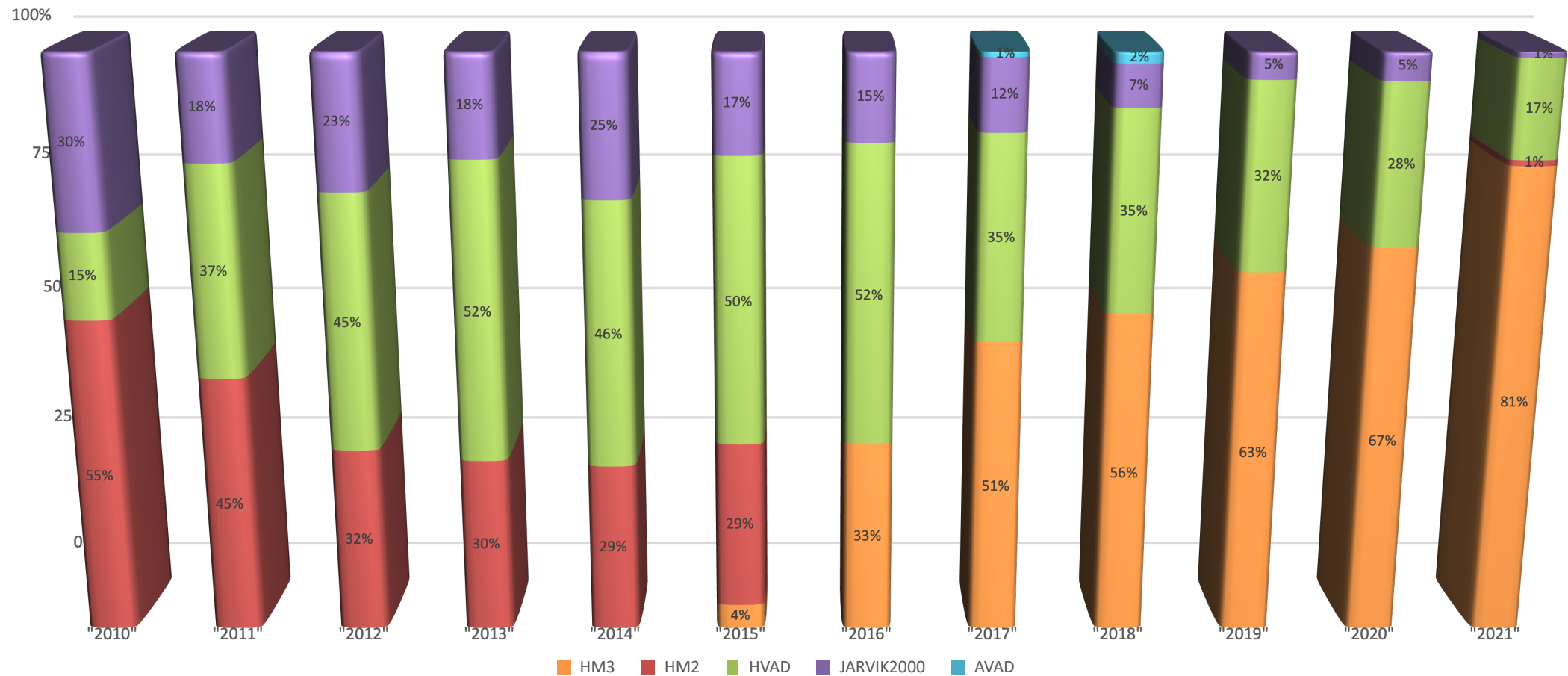
Approach

Sternotomy	802 (75.9%)
Left Thoracotomy	82 (7.8%)
Less Invasive Approach	173 (16.4%)

- *Mini-sternotomy* (46,2%)
- *RAT* (35,8%)
- *Subclavian Artery* (18%)

Concomitant Cardiac Procedures	176 (17.0%)
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Devices by year (%)



Post-Operative Outcomes

- *Discharged* 882 (83.3%)
- *30-Day Mortality* 90 (8.5%)
- *LOS (median)* 30 days

Post-Operative Outcomes

RV Failure	185 (18.0%)
Arrhythmia	178 (17.6%)
Ischemic Stroke	126 (11.9%)
Hemorrhagic Stroke	109 (10.7%)
GI Bleeding	130 (12.8%)
Driveline Infection	318 (30.0%)
Device Infection	26 (2.5%)
Device Malfunction	106 (10.5%)

Logistic Regression for 30-Day Mortality

Predictor	Odds ratio	95% Confidence Interval		p
		Lower	Upper	
Age	1.0232	0.98357	1.064	0.255
Female sex	0.7648	0.31254	1.871	0.557
INTERMACS 1	2.6973	1.33437	5.452	0.006
Indication:				
BTC – BTT	1.8670	0.88475	3.940	0.101
DT – BTT	1.5357	0.69567	3.390	0.288
Device:				
AVAD (Reliant Heart) – HM3	5.8510	0.45251	75.656	0.176
HM2 – HM3	0.8474	0.35440	2.026	0.710
HVAD – HM3	0.7932	0.36886	1.706	0.553
JARVIK2000 – HM3	1.2058	0.47339	3.072	0.695
Temporary RVAD	1.1103	0.19359	6.368	0.907
Redo Surgery	0.8455	0.45244	1.580	0.599
Sternotomy	1.0744	0.51699	2.233	0.848
ECMO	0.8455	0.25720	2.779	0.782
Other Cardiac Procedures	1.4804	0.69160	3.169	0.312

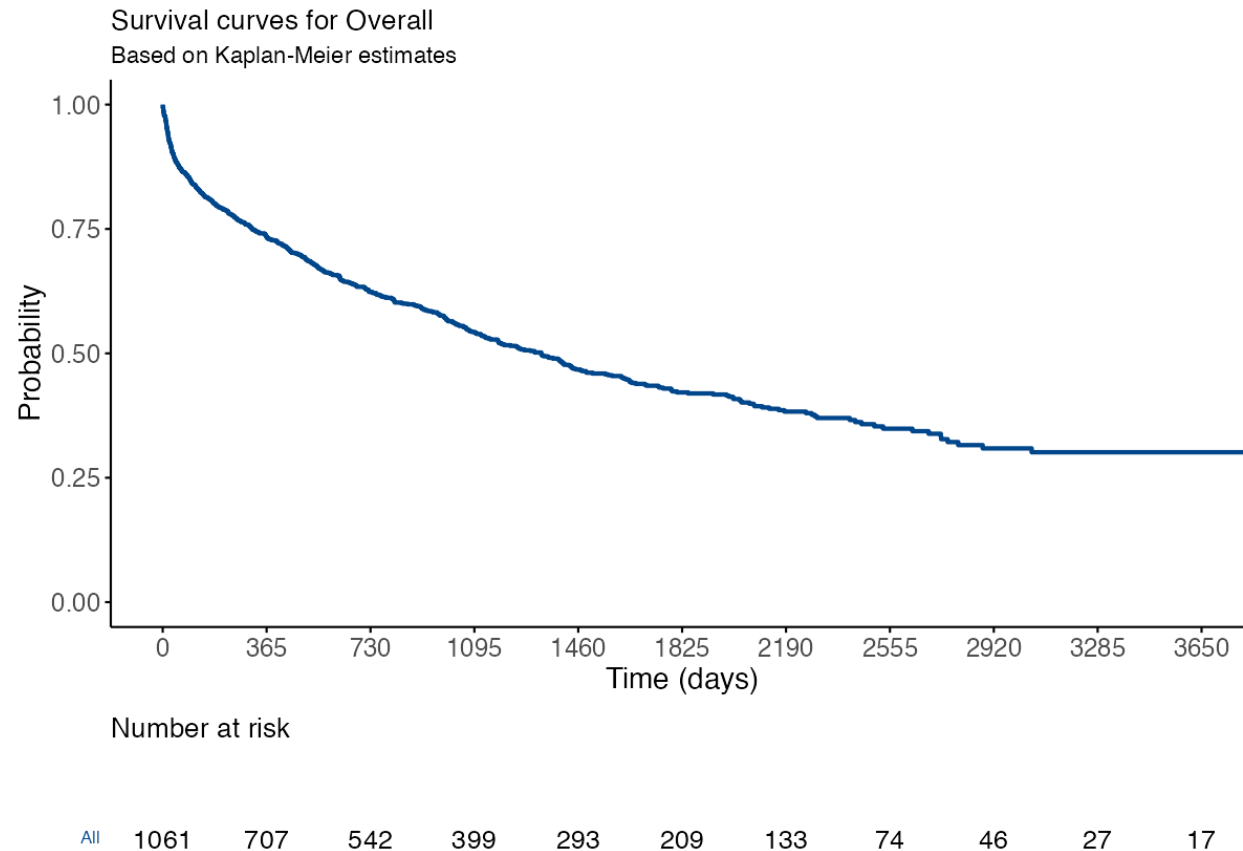


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Survival-analysis

Median Survival: 3,6y

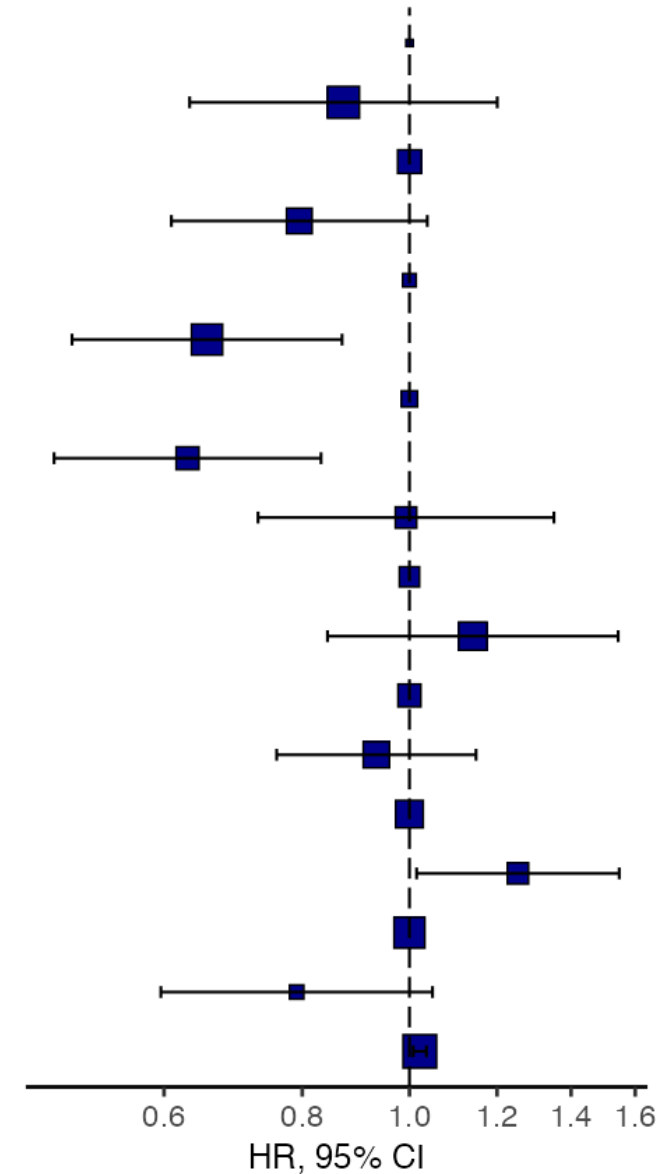


Survival	%
1 year	73.5
3 years	54.3
5 years	42.1

Multivariable Cox Regression for Survival

Survival: HR (95% CI, p-value)

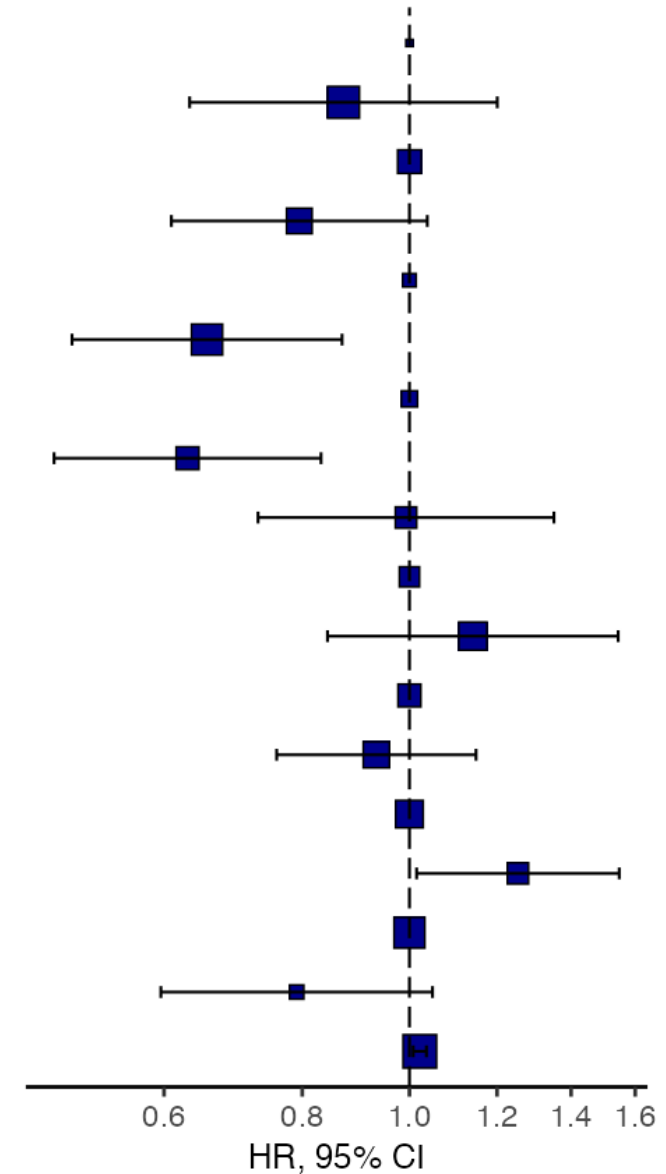
Sex	F	-
	M	0.87 (0.63-1.20, p=0.400)
Year_cat	2010-2015	-
	2016-2021	0.80 (0.61-1.04, p=0.092)
INTERMACS_1_vs_other	1	-
	> 1	0.66 (0.50-0.87, p=0.003)
Indication	BTC	-
	BTT	0.63 (0.48-0.83, p=0.001)
	DT	0.99 (0.73-1.35, p=0.964)
Device	HM3	-
	Other	1.14 (0.84-1.54, p=0.393)
Diagnosis_CMD2_vs_other	0	-
	1	0.93 (0.76-1.15, p=0.515)
redo_surgery	NO	-
	SI	1.25 (1.02-1.55, p=0.036)
mini_outflow	NO	-
	SI	0.79 (0.60-1.05, p=0.104)
Age	-	1.02 (1.01-1.04, p=0.002)



Multivariable Cox Regression for Survival

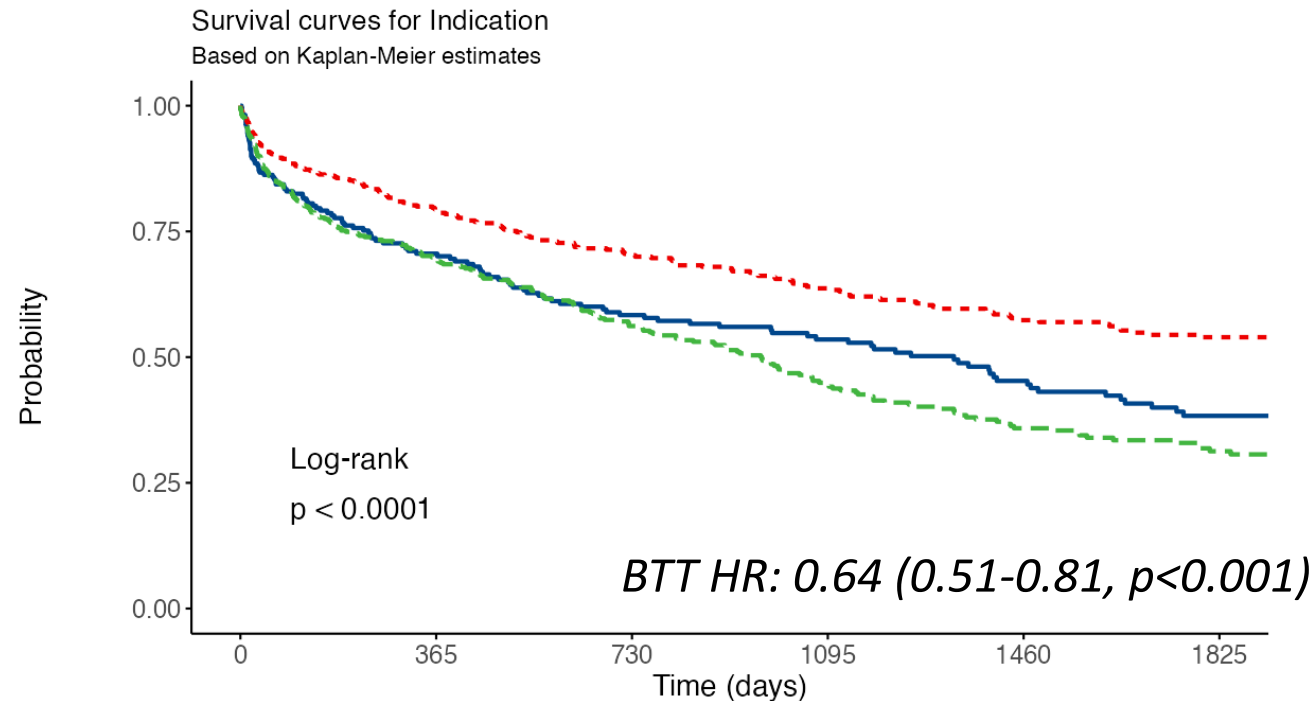
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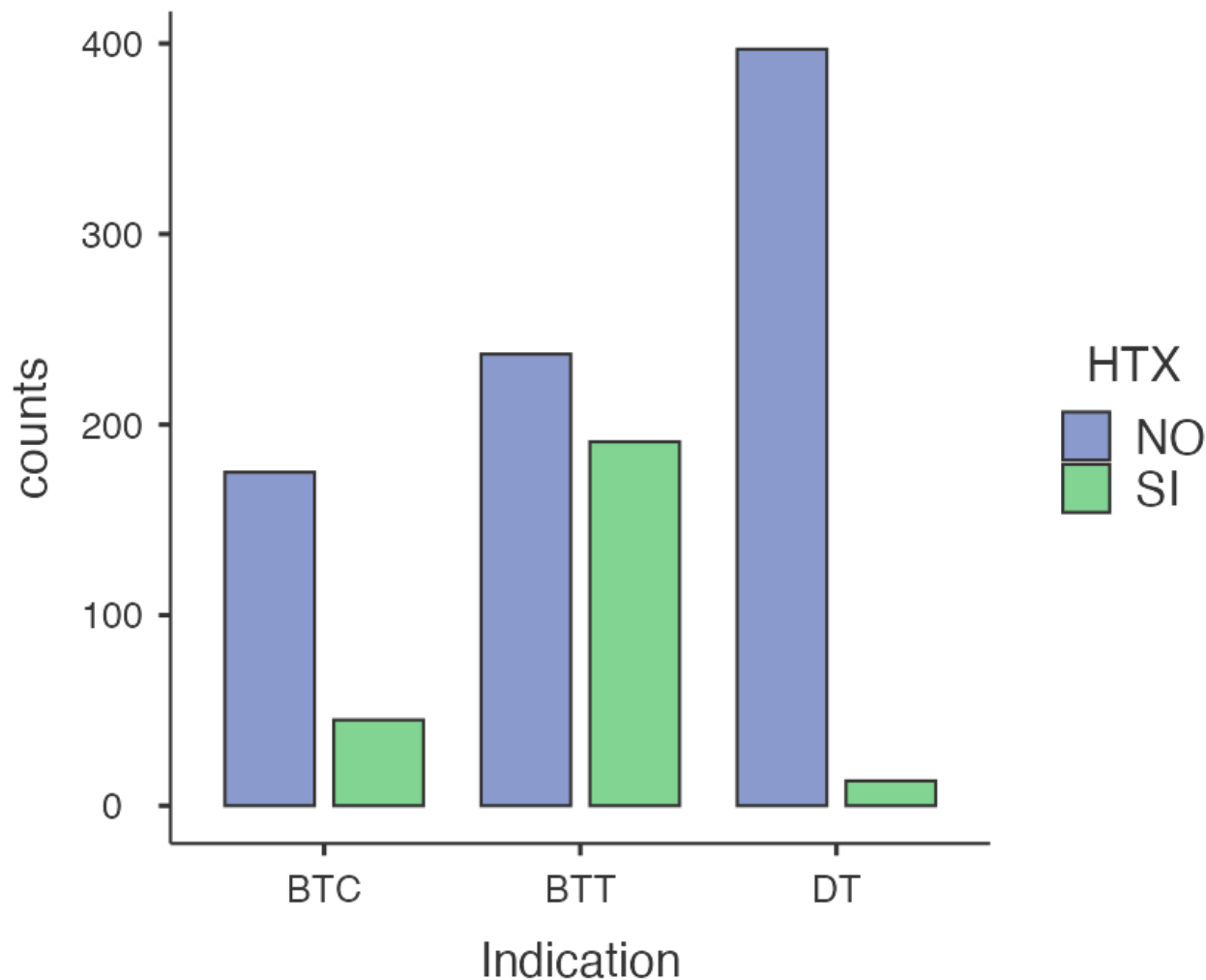
Survival-analysis by Indication

Survival	BTT	BTC	DT
1 year	78.9%	70.6%	69.6%
3 years	63.7%	53.5%	44.5%
5 years	54.0%	38.3%	31.2%



	Number at risk					
Indication=BTC	220	137	104	84	63	44
Indication=BTT	428	315	254	199	148	113
Indication=DT	410	254	183	116	82	52

Role of HTx in pts with LVAD



A total of 250 patients included in our analysis were transplanted:

- 45% of BTT
- 20% of BTC
- 3% of DT

The overall median time from LVAD implantation to HT was 502 [289-929] days and it was significantly shorter for BTT patients (477 days) compared to BTC (571 days) or DT patients (963 days) ($p=0.003$).

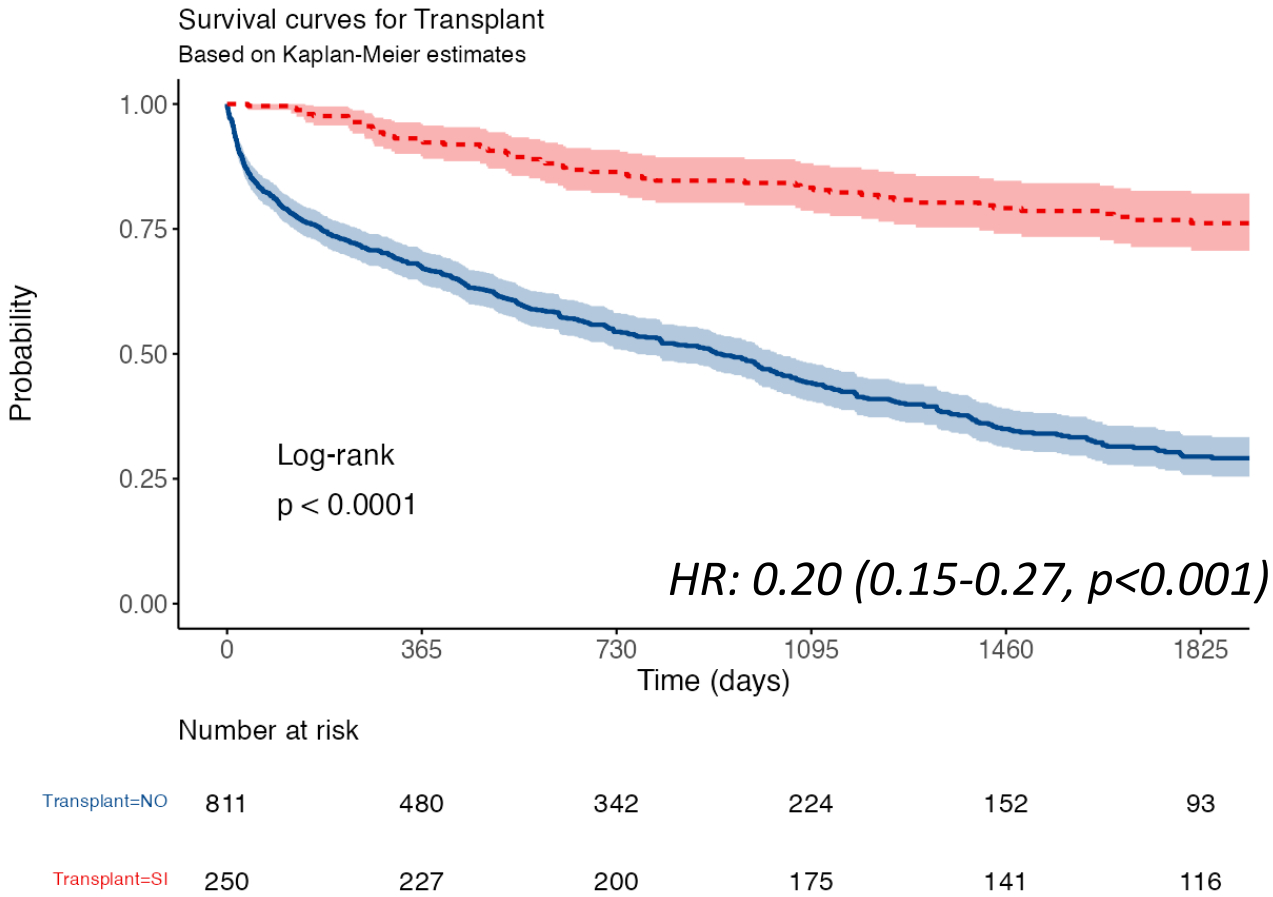
Survival	Tranplanted	Not Transplanted
1 year	92.7%	67.4%
3 years	83.3%	44.2%
5 years	76.1%	29.4%

Overall
(N=1061)

Transplant

NO 811 (76.4%)

SI 250 (23.6%)



Survival-analysis by INTERMACS Class

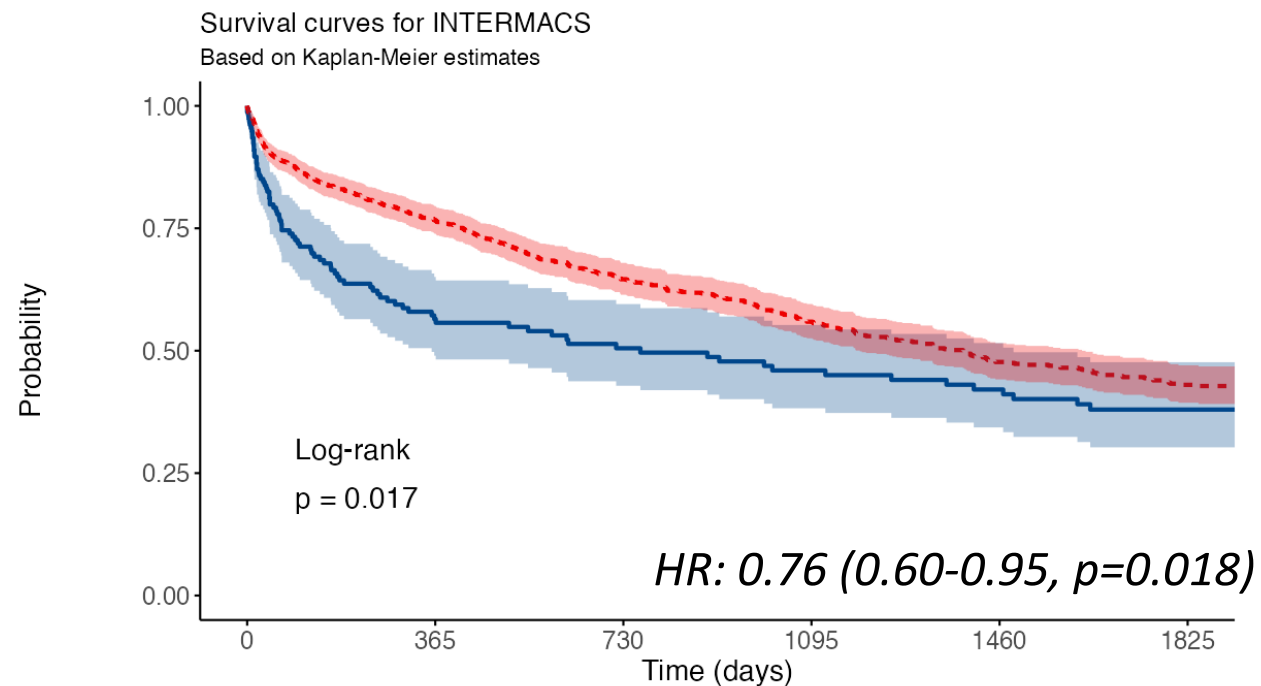
Survival	INTERMACS 1	INTERMACS >1
1 year	56.4%	76.7%
3 years	46.0%	55.9%
5 years	38.0%	43.0%

INTERMACS

Overall
(N=1061)

1 156 (14.8%)

>1 899 (85.2%)



Number at risk						
INTERMACS=1	156	75	57	48	43	28
INTERMACS=>1	899	630	483	351	250	181

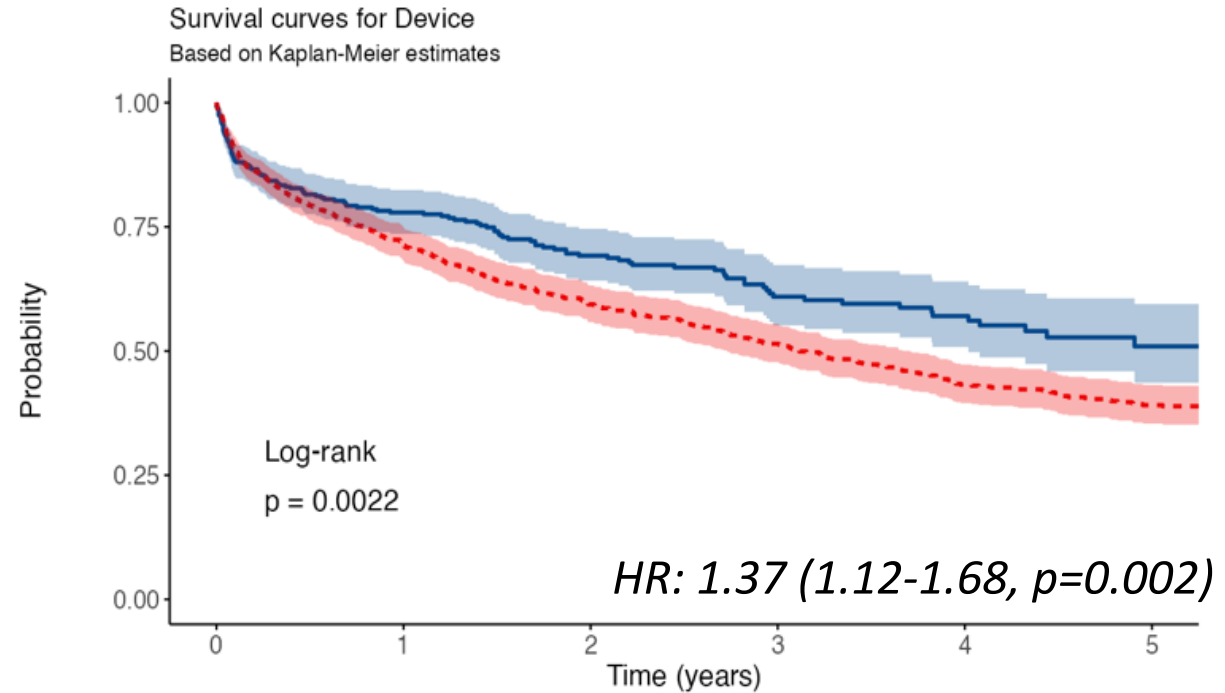
Survival-analysis by Devices

Survival	HeartMate3	Others
1 year	77.9%	71.5%
3 years	60.9%	51.5%
5 years	50.9%	39.1%

Overall
(N=1061)

Device

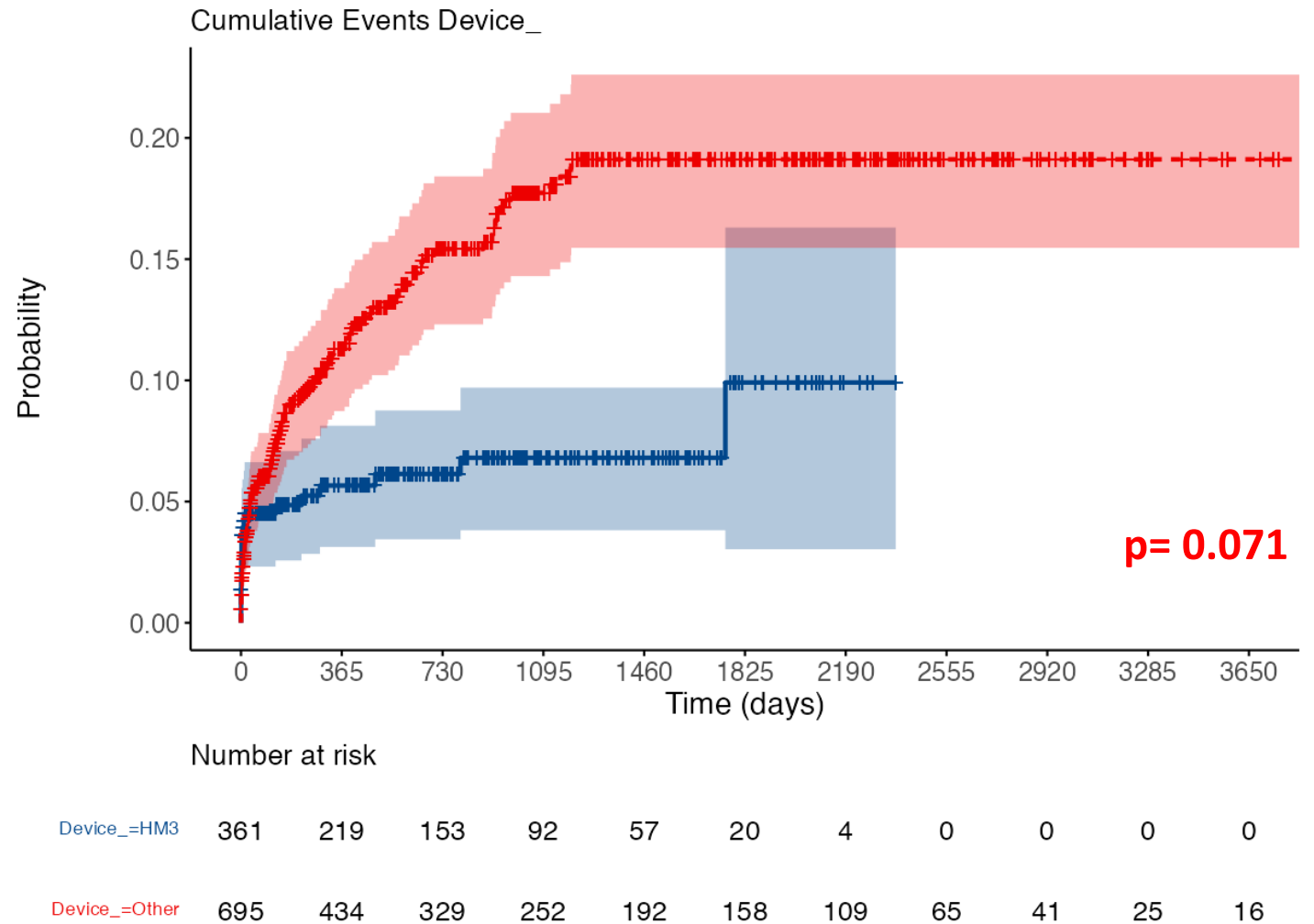
HeartMate3 363 (34.2%)
Others 698 (65.8%)



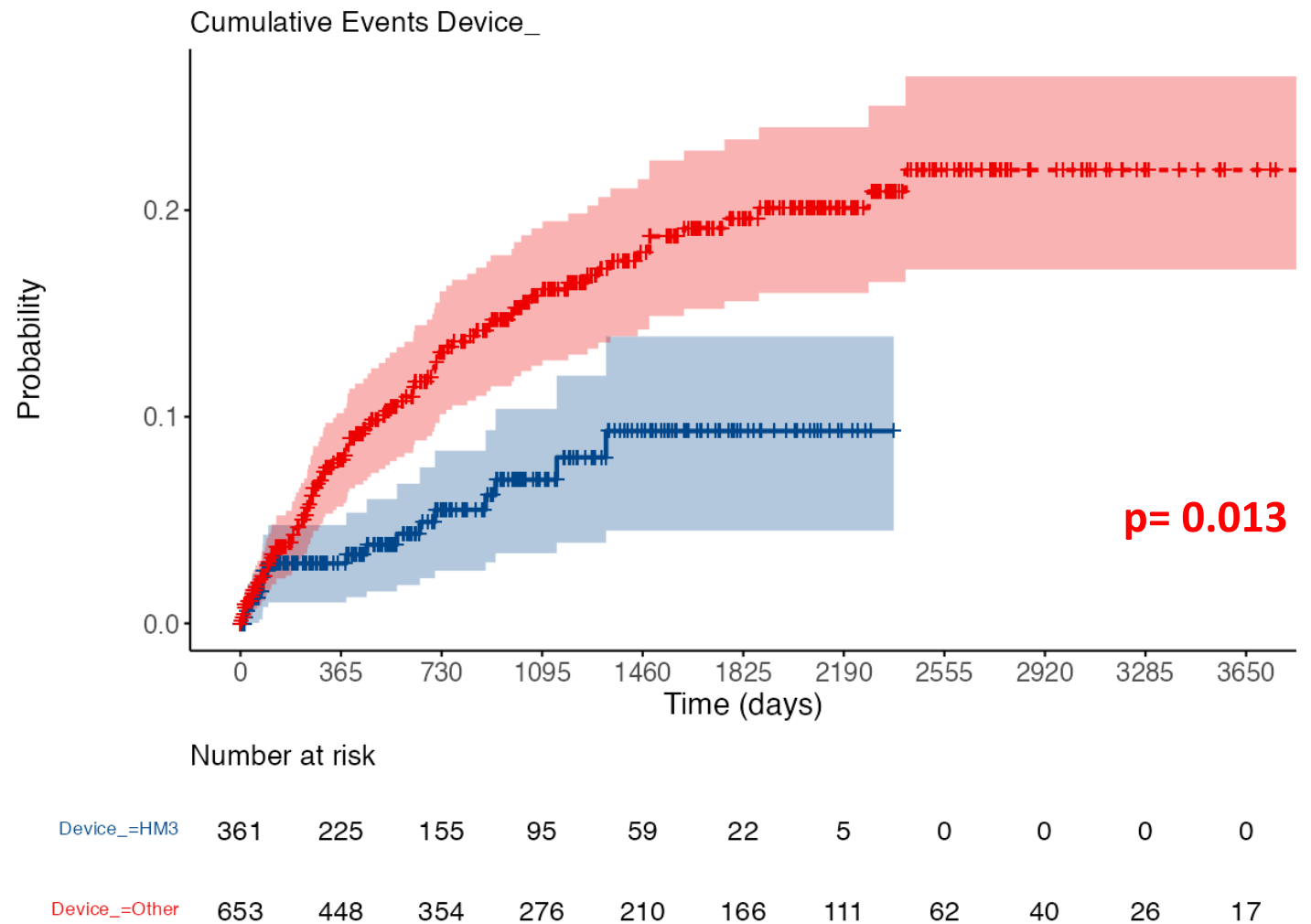
Number at risk						
Device=HM3	363	226	158	97	61	22
Device=Other	698	481	384	302	232	187

Group	Ischemic Stroke	Hemorrhagic Stroke	GI Bleeding	Pump Thrombosis
	IR (95% CI)	IR (95% CI)	IR (95% CI)	IR (95% CI)
	(per 100 patient-years)	(per 100 patient-years)	(per 100 patient-years)	(per 100 patient-years)
Overall (n=1061)	4.3 (3.6-5.1)	3.7 (3.1-4.5)	4.5 (3.7-5.3)	2.9 (2.3-3.6)
Device				
HeartMate 3 (n=363)	3.3 (2.1-5)	2.5 (1.5-4)	3.2 (2-4.8)	0.4 (0.1-1.2)
HVAD (n=403)	5.1 (3.9-6.6)	4.8 (3.6-6.2)	5.1 (3.9-6.6)	5.1 (3.9-6.6)
Other (n=295)	4.0 (2.9-5.4)	3.3 (2.3-4.7)	4.5 (3.3-6)	2.1 (1.3-3.1)
P-value	0.071	0.013	0.049	<0.001

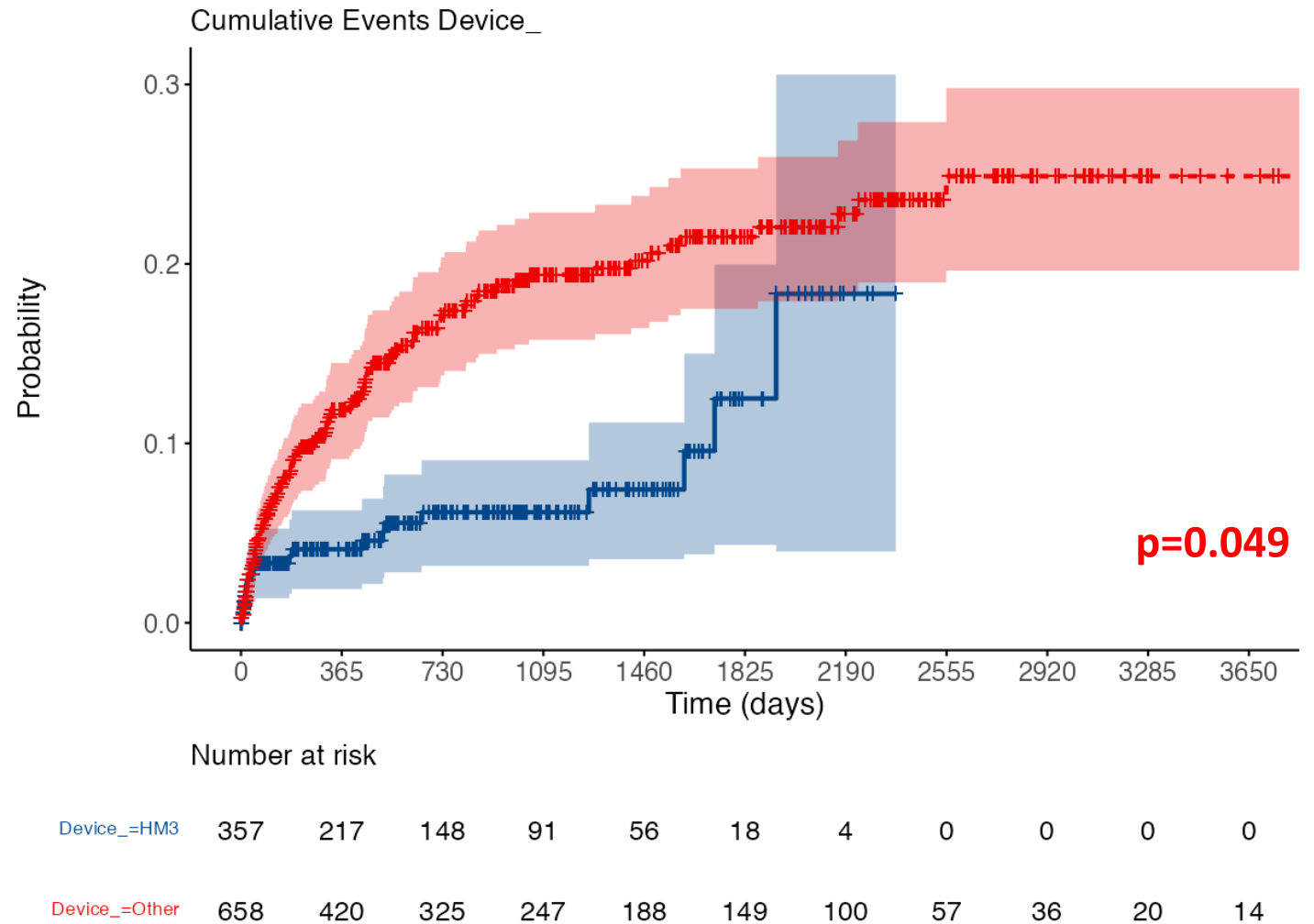
Ischemic Stroke



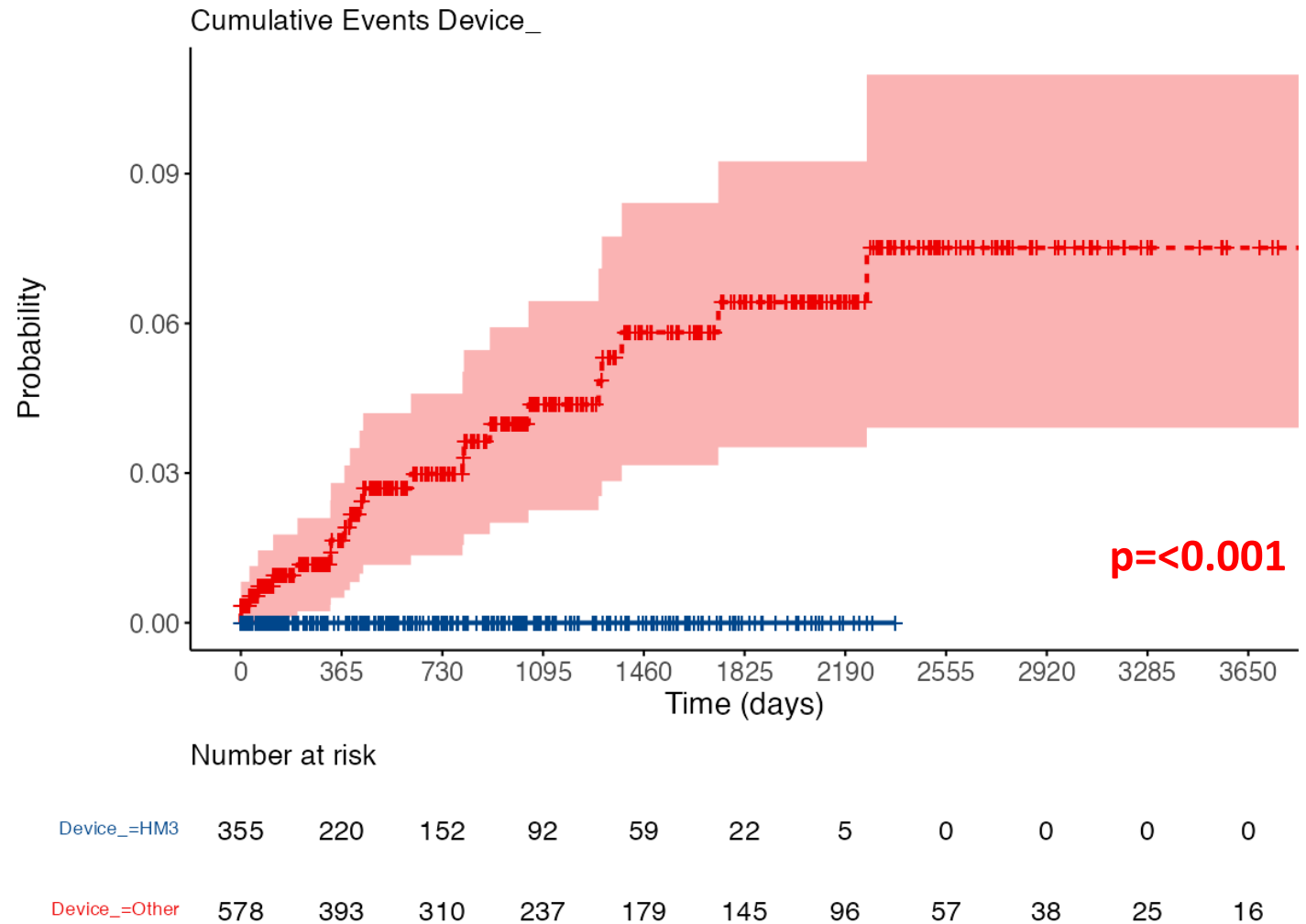
Hemorrhagic Stroke



GI Bleeding



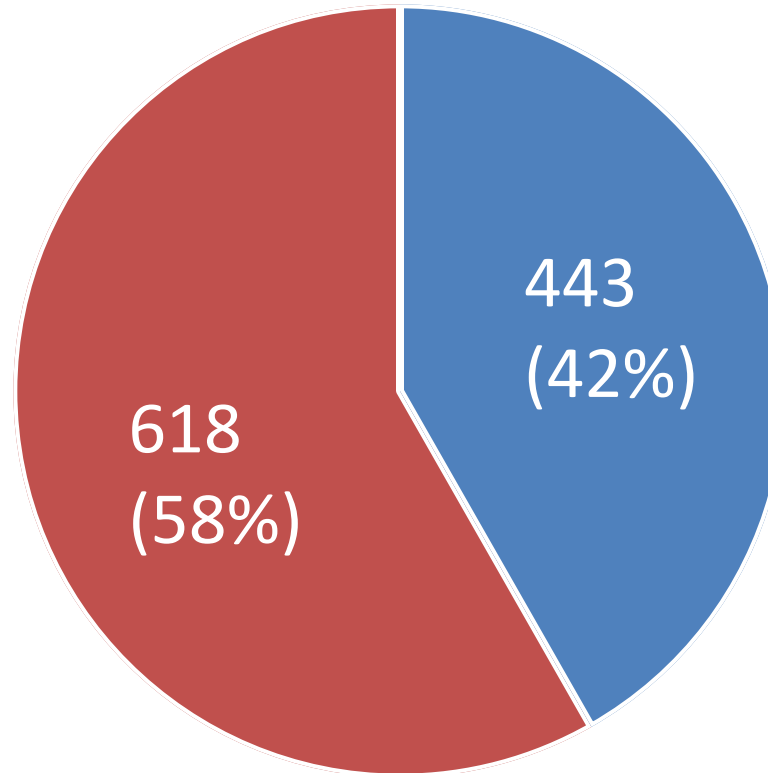
Pump thrombosis



Analysis by Year of Implantation

Durable MCS by Year

- 2010-2015
- 2016-2021



Pre-Operative and Intra-operative Characteristics

	2010-2015 Era (n=443)	2016-2021 Era (n=618)	p-value
Age, median (IQR), years	60 (47-73)	62 (50-74)	<0.001
Female, n (%)	44 (9.9)	74 (12)	0.3
Diagnosis, n (%)			0.41
CM Dilatative-Secondary	251 (57)	354 (57)	
CM Dilatative-Primary	181 (41)	235 (38)	
CM Hypertrophic	5 (1.1)	11 (1.8)	
Post-Myocarditis	3 (0.7)	11 (1.8)	
Congenital Heart Defect	0	3 (0.5)	
CM Restrictive	1 (0.2)	1 (0.2)	
CM Arrhythmogenic	0	1 (0.2)	
Heart Transplant Rejection	0	1 (0.2)	
INTERMACS class, n (%)			<0.001
1	75 (17)	81 (13)	
2	121 (27)	124 (20)	
3	140 (32)	268 (44)	
4	106 (24)	133 (22)	
5	0	7 (1.1)	
Indication, n (%)			<0.001
BTT	216 (49)	212 (34)	
DT	151 (34)	259 (42)	
BTC	74 (17)	146 (24)	

	2010-2015 Era (n=443)	2016-2021 Era (n=618)	p-value
Re-do Surgery, n (%)	110 (31)	172 (40)	0.008
Device, n (%)			<0.001
AVAD (Reliant Heart)	0	3 (0.5)	
HeartMate II	150 (34)	1 (0.2)	
HeartMate 3	5 (1.1)	358 (58)	
Heartware	195 (44)	208 (34)	
Jarvik2000	93 (21)	48 (7.8)	
Other procedures, n (%)	63 (15)	113 (19)	0.073
Temporary RVAD, n (%)	2 (0.5)	25 (4.0)	<0.001
Implant assisted, n (%)			0.10
Cardiopulmonary bypass	368 (84)	535 (87)	
ECMO	31 (7.0)	25 (4.1)	
Off-pump	41 (9.3)	57 (9.2)	
Approach, n (%)			0.16
Sternotomy	322 (73)	480 (78)	
Left Thoracotomy	35 (8.0)	47 (7.6)	
Minimally-Invasive	83 (19)	90 (15)	

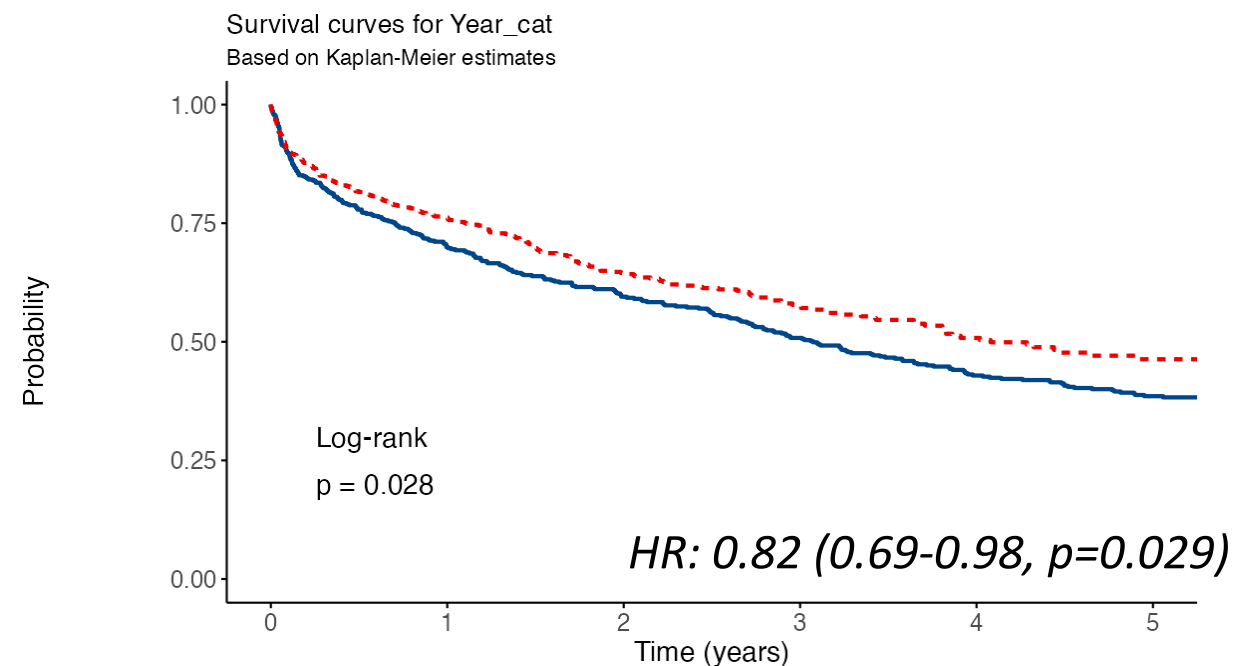
Survival	2010-2015	2016-2021
1 year	70.0%	76.2%
3 years	50.8%	57.4%
5 years	38.5%	46.3%

Overall
(N=1061)

Years

2010-2015 443 (41.8%)

2016-2021 618 (58.2%)



Year_cat=2010-2015	443	309	261	222	181	155
Year_cat=2016-2021	618	398	281	177	112	54

Conclusions

- The ITAMACS represents the first national registry for durable MCS in Italy.
- In the present report, we described the national intracorporeal LVAD implantation activity (1061 pts in a 12-year timeframe)
- The overall survival rate at 1, 3 and 5 years was 73%, 54% and 42% respectively.
- In the most recent era, the prognosis of LVAD patients has further ameliorated, matching the highest international standards.
- On the other hand, the ITAMACS has revealed that national outcomes of patients in the most compromised INTERMACS classes, as well as those implanted as DT, are still suboptimal.
- ITAMACS is still proving to be a powerful tool:
 - to monitor d-MCS italian program,
 - for a better understanding of the national scenario, for the optimization of the durable LVAD program and to improve the quality of care for patients.

First Italian multicentre registry for Mechanically Assisted Circulatory Support (ITAMACS) report: 12-year experience of over 1000 durable LVAD patients

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Conclusion

ITAMACS is the first national registry reporting real-world outcomes of durable LVAD therapy in Italy. These data provide an overview of national practice and may support optimization of LVAD programs and patient care.