FIRST ANNOUNCEMENT

BEYOND THE SLIDES 2015
1st UDINE ECMO WORKSHOP

DECEMBER 18-19, 2015 - AUDITORIUM HYPO ALPE ADRIA - TAVAGNACCO (UD)

ECMO as bridge to heart transplantation

I. Vendramin, A. Lechiancole

Cardiothoracic Department
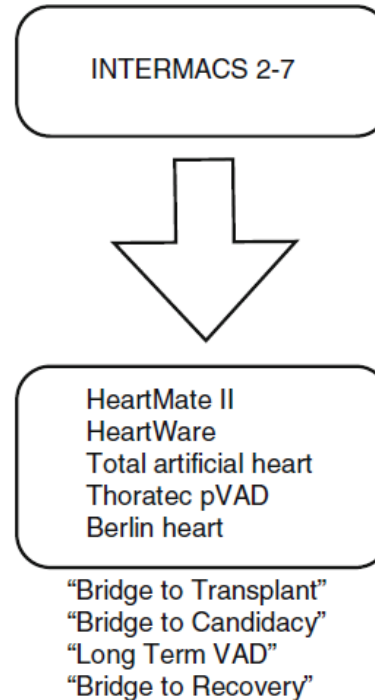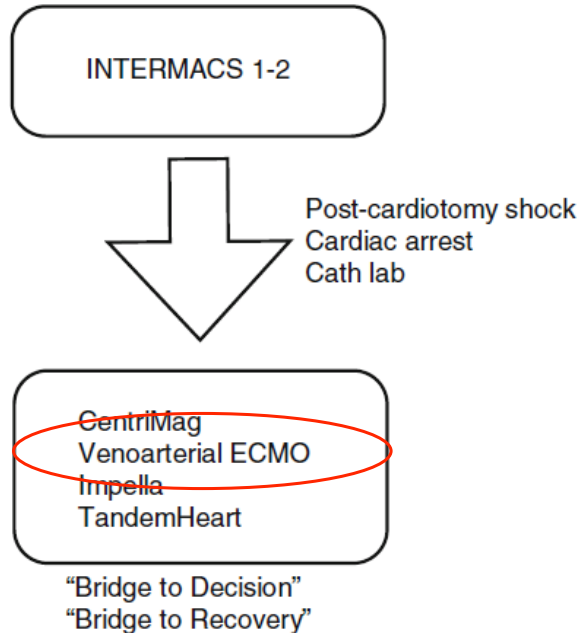University Hospital, S. Maria della Misericordia
Udine

ECMO-Extracorporeal Life Support in Adults

Treatment Options for End-Stage Cardiac Failure

Gurmeet Singh

F. Sangalli et al. (eds.), *ECMO-Extracorporeal Life Support in Adults*

INTERMACS 1-2

↓

Post-cardiotomy shock
Cardiac arrest
Cath lab

CentriMag
Venoarterial ECMO
Impella
TandemHeart

"Bridge to Decision"
"Bridge to Recovery"

Unselected patients

INTERMACS 2-7

↓

HeartMate II
HeartWare
Total artificial heart
Thoratec pVAD
Berlin heart

"Bridge to Transplant"
"Bridge to Candidacy"
"Long Term VAD"
"Bridge to Recovery"

Refractory Cardiogenic Shock

INTERMACS profile	Short description
1	Critical cardiogenic shock
2	Progressive decline on inotropes
3	Stable, but inotrope dependent
4	Symptoms at rest; home on oral therapy
5	Exertion intolerant
6	Exertion limited
7	Advanced NYHA class III symptoms

ECMO as a bridge to decision: Recovery, VAD, or heart transplantation?

N. Rousse [a,b,e,1], F. Juthier [a,b,e,1], C. Pinçon [c], I. Hysi [a], C. Banfi [a], E. Robin [d], G. Fayad [a], B. Jegou [a], A. Prat [a], A. Vincentelli [a,b,e,*]
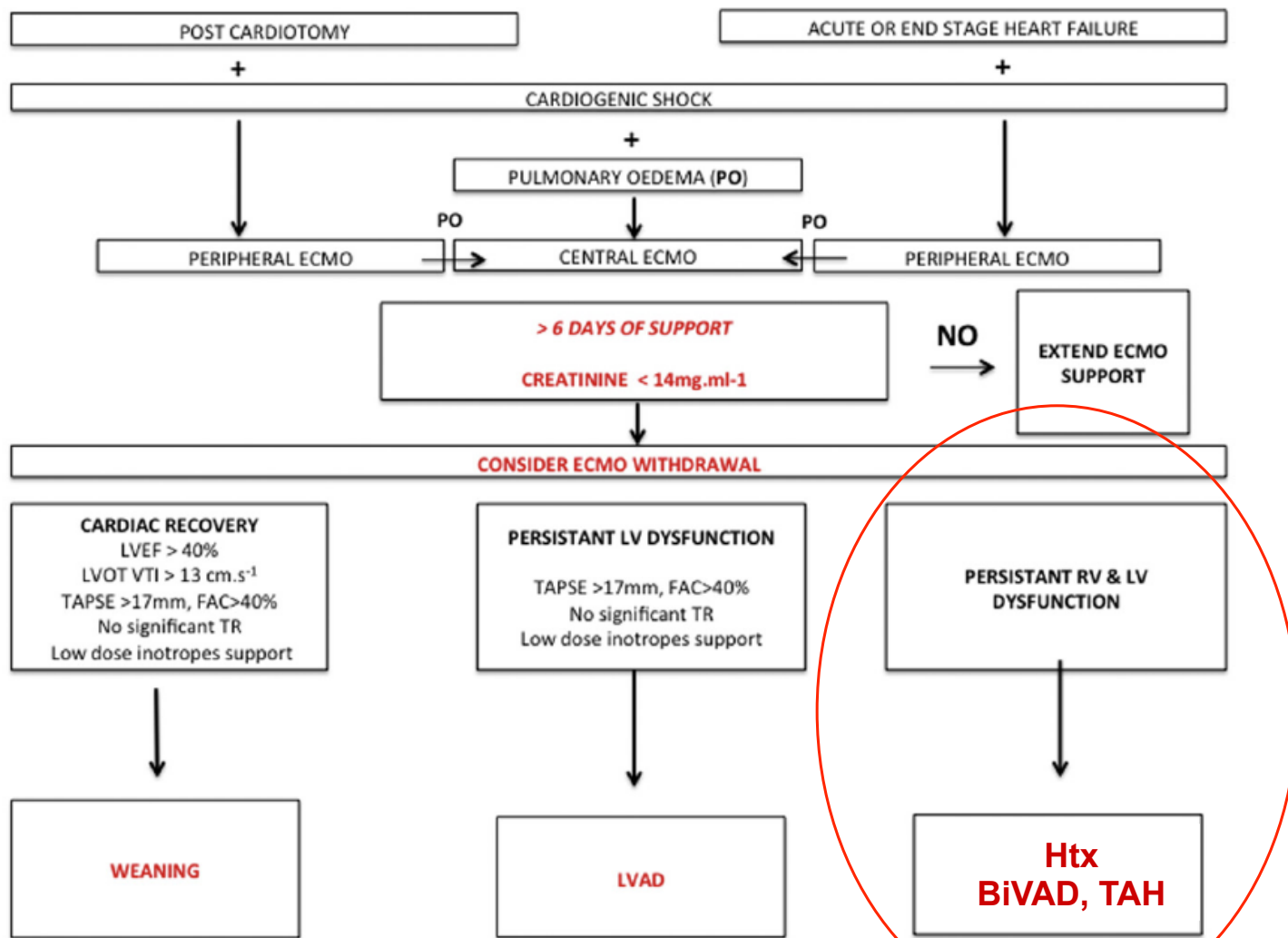
Among adult Heart Transplants, percentage of patients bridged with VA ECMO is increasing over time

	1992-2003 (N=48,061)	2004-2008 (N=17,366)	2009-6/2014 (N=19,770)	p-value
Pre-operative support (multiple items may be reported)				
Hospitalized at time of transplant	58.9%	46.2%	43.8%	<0.0001
On IV inotropes	54.4%[1]	44.6%	39.9%	<0.0001
Ventilator	3.3%	3.0%	2.3%	<0.0001
IABP	6.5%	7.0%	6.2%	0.0865
Mechanical circulatory support	22.2%[2]	26.0%	43.0%	<0.0001
LVAD	13.2%[2]	21.8%	36.6%	<0.0001
RVAD	-	4.4%[3]	3.2%	<0.0001
TAH	0.0%[2]	0.5%	1.4%	<0.0001
ECMO	0.3%[4]	0.9%	1.2%	<0.0001

[1] Based on 4/1994-2003 transplants.
[2] Based on 11/1999-2003 transplants.
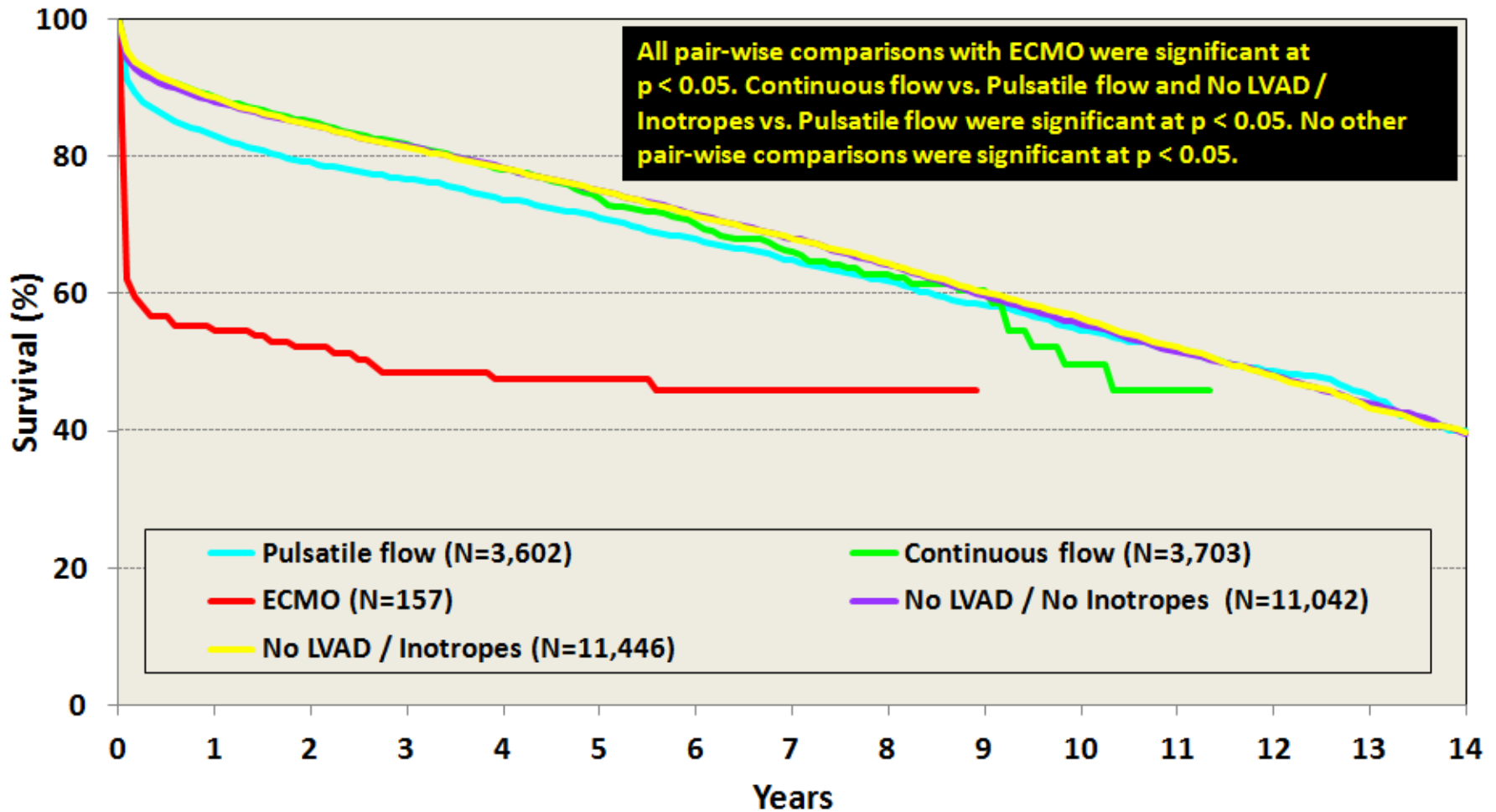[3] Based on 2005-2008 transplants.
[4] Based on 5/1995-2008 transplants.

Adult Heart Transplants
Kaplan-Meier Survival by VAD usage
(Transplants: January 1999 – June 2013)

All pair-wise comparisons with ECMO were significant at p < 0.05. Continuous flow vs. Pulsatile flow and No LVAD / Inotropes vs. Pulsatile flow were significant at p < 0.05. No other pair-wise comparisons were significant at p < 0.05.

Legend:
- Pulsatile flow (N=3,602)
- ECMO (N=157)
- No LVAD / Inotropes (N=11,446)
- Continuous flow (N=3,703)
- No LVAD / No Inotropes (N=11,042)

Kaplan-Meier intermediate-term survival by pre-transplant MCS use
(Transplants: January 2009 – June 2013)

All pair-wise comparisons with ECMO were significant at $p < 0.05$. No other pair-wise comparisons were significant at $p < 0.05$.

- LVAD Pulsatile (N=145)
- LVAD+RVAD Pulsatile (N=164)
- No LVAD, No Inotropes (N=2,998)
- LVAD Continuous (N=2,952)
- ECMO (N=72)
- No LVAD, Inotropes (N=3,335)
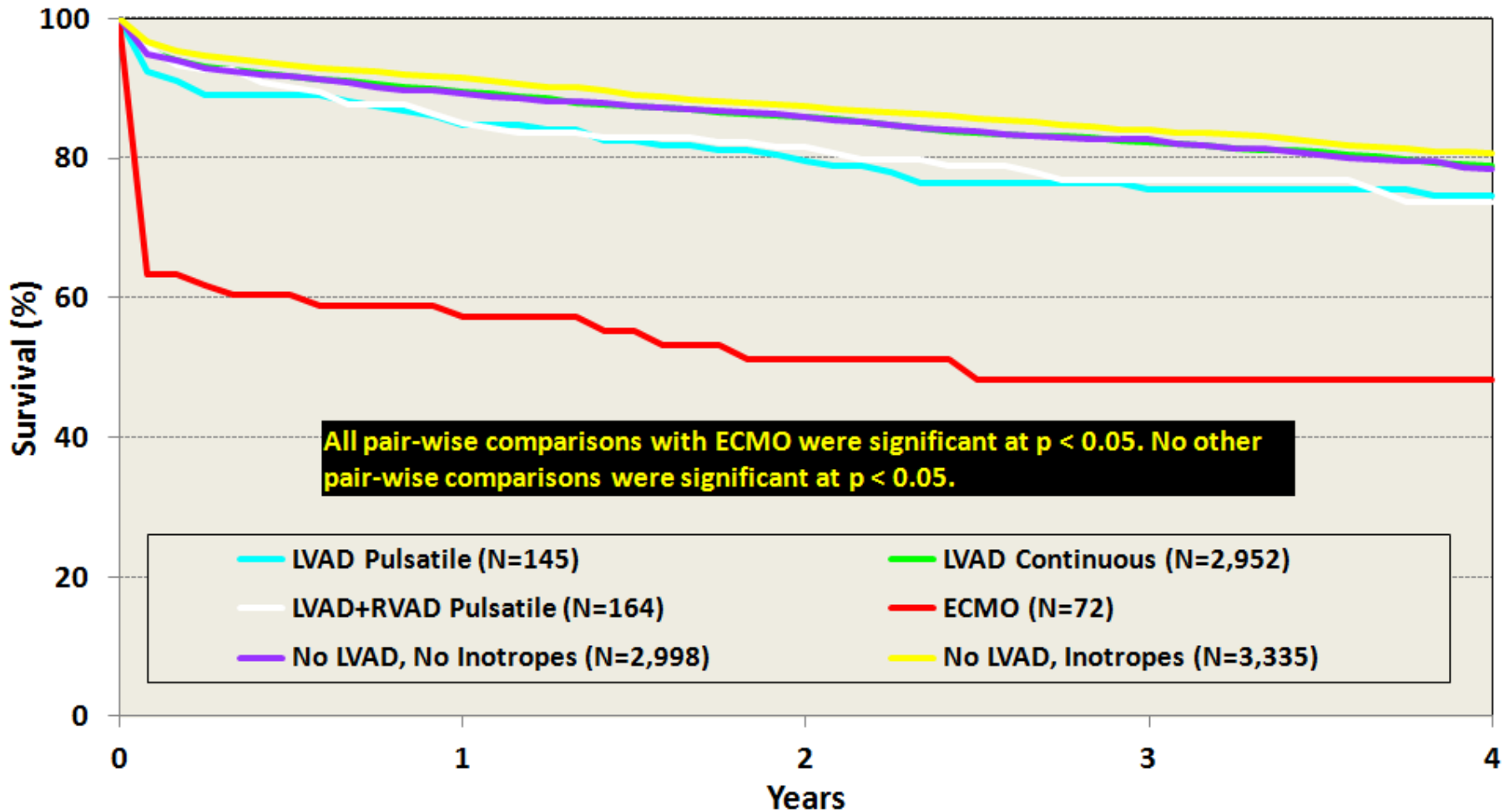
Survival Benefit From Transplantation in Patients Listed for Heart Transplantation in the United States

Tajinder P. Singh, MD, MSc,*† Carly E. Milliren, MPH,‡ Christopher S. Almond, MD, MPH,*† Dionne Graham, PhD*†‡

Boston, Massachusetts

Predictor	Coefficient (90-Day Mortality)	Odds Ratio (95% CI)	Coefficient (1-Year Mortality)	Odds Ratio (95% CI)
Age (reference: 18–59 yrs)				
60–69 yrs	0.48	1.6 (1.3–2.1)	0.37	1.45 (1.2–1.8)
≥70 yrs	0.46	1.6 (0.8–3.1)	0.31	1.36 (0.8–2.3)
Diagnosis				
CHD	1.46	4.3 (2.4–7.7)	1.06	2.87 (1.7–4.8)
Ischemic CMP	0.37	1.5 (1.1–1.8)	0.28	1.32 (1.1–1.6)
Restrictive	0.73	2.1 (1.1–3.9)	0.93	2.54 (1.6–4.0)
Ventilation	0.90	2.5 (1.6–3.9)	0.63	1.88 (1.3–2.8)
Mechanical support (reference: none)				
BIVAD or TAH	0.85	2.4 (1.5–3.6)	0.76	2.13 (1.5–3.0)
LVAD	0.45	1.6 (1.2 2.0)	0.36	1.43 (1.2–1.85)
ECMO	2.21	9.2 (4.6–18.1)	1.70	5.49 (2.9–10.5)
Non-ECMO temporary support	1.54	4.7 (1.8–11.9)	1.45	4.25 (1.9–9.5)
GFR (reference: ≥90 ml/min/1.73 m^2)				
30–59 ml/min/1.73 m^2	0.41	1.5 (1.2–1.9)	0.29	1.34 (1.1–1.6)
<30 ml/min/1.73 m^2	0.65	1.9 (1.1–3.3)	0.55	1.74 (1.1–2.7)
Dialysis	0.92	2.5 (1.4–4.4)	0.96	2.60 (1.7–4.0)
Intercept	−3.69	–	−2.86	–

Dilated CMP (n = 4,773)	Ischemic CMP (n = 3,704)	Other (n = 1,682)	Total (n = 10,159)

Predictors of mortality

Recent studies describing the outcome of ECMO-assisted refractory cardiac shock

	% of successful weaning	Mortality	Conclusions/comments
Unosawa et al. [5]	61.7 % Mean ECMO duration 64±62 h	66 % at 30 days (tot) (*51.7% in ECMO weaned*) 70.2 % at 1 year 82.4 % at 5 years	Incomplete sternum closure predicts mortality during ECMO; intraoperative CPB time is significantly different among W/NW ECMO >48 h is a predictor of mortality post weaning; age, preop-LVEF, EuroSCORE, duration of ECMO, and peak creatine level during ECMO are significantly different among WS/WNS
Slottosch et al. [6]	62.3 % Mean ECMO duration 79±57 h	70 % at 30 days (tot) (*52.1% in ECMO weaned*)	Predictors of mortality: age, lactates at 24-h ECMO, duration of ECMO support, GI complications, any ECMO-related complication
Aissaoui et al. [13]	40 % (+12 pts bridged to VAD/transplant)		Echographic predictors of successful weaning: LVEF >20–25 %, aortic VTI ≥10 cm, mitral annulus peak systolic velocity TDSa ≥6 cm/s at minimal ECMO flow
Chang et al. [14]	(only weaned pts)	26 % in-hospital	Predictors of in-hospital mortality: MAP and SOFA score (cutoff value 13) on the day of ECMO removal, daily urine amount on the second day after weaning
Formica et al. [15]	69 % Mean ECMO duration 190±127 h	47.6 % at 30 days 61.9 % in-hospital	Blood lactate levels at 48 h of ECMO support and number of PRBCs transfused are associated with 30-day mortality
Rastan et al. [16]	63 % (+20 pts bridged to VAD/transplant) Mean ECMO duration 79±68 h	75.2 % in-hospital 82.4 % at 6 months 83.5 % at 1 years 86.3 % at 5 years (20 pts bridged to VAD/transplant)	Predictors of in-hospital mortality: age, diabetes, preoperative chronic kidney disease, obesity, lactates, EuroSCORE >20 %
Luo et al. [10]	60 % (+5 pts bridged to transplant) Mean ECMO duration 126±104 h	42 % in-hospital (5 pts bridged to transplant)	CRRT on ECMO is a predictor of mortality No significant difference between ECMO and ECMO+IABP

Predictors of mortality

Bakhtiary et al. [3]	55 % (+7 pts bridged to VAD/transplant) Mean ECMO duration 154 ± 108 h	53 % at 30 days 71 % in-hospital 78 % at 3 years	Predictors of hospital survival: absence of pulmonary hypertension, absence of diabetes, use of IABP
Chen et al. [8]	69.4 %	66.7 % in-hospital (tot) (52 % in ECMO weaned)	S vs NS have lower inotropic score, reduced blood lactate level, shorter CPR duration, surgical revascularization, reduced SOFA score
Zhang et al. [17]	43.7 % Mean ECMO duration 65 ± 41 h	68.75 % at 30 days 75 % in-hospital	Preop-LVEF and lactates, CK-MB, and CK-MB/TOT CK at 48-h ECMO are significantly different among W/NW pts CK-MB/TOT CK at 48-h ECMO predicts mortality on ECMO
Doll et al. [18]	61 % (+12 pts bridged to VAD/transplant) Mean ECMO duration 62 ± 53 h	76 % at 30 days 82 % at 5 years	Higher mortality for CABG + aortic valve replacement vs other surgery Predictors of in-hospital survival are younger age, absence of preoperative AMI, absence of DM, use of IABP
Smedira et al. [4]	35 % (+48 pts bridged to transplant)	24 % at 3 days 62 % at 30 days (tot) (48 % in ECMO weaned) 76 % at 5 years (tot) (40 % in ECMO weaned) (48 pts bridged to transplant)	Risk factors for mortality: age, thoracic aorta surgery, reoperation, nonuse of IABP

W weaned patients, *NW* not-weaned patients, *S* survivors, *NS* nonsurvivors, *WS* weaned and survived, *WNS* weaned but not survived (died after ECMO)

Evaluation of Outcome Scoring Systems for Patients on Extracorporeal Membrane Oxygenation

Comparison of Calibration and Discrimination of the Scoring Methods in Predicting Hospital Mortality

Model	Calibration			Discrimination		
	Hosmer-Lemeshow χ^2	df	p Value	AUROC $\pm$ SE	95% CI	p Value
APACHE IV	6.972	8	0.540	0.922 $\pm$ 0.030	0.863–0.982	<0.001
APACHE III	22.013	8	0.005	0.907 $\pm$ 0.038	0.833–0.981	<0.001
APACHE II	8.114	8	0.422	0.898 $\pm$ 0.033	0.833–0.963	<0.001
SOFA score	8.228	8	0.411	0.870 $\pm$ 0.041	0.790–0.949	<0.001
RIFLE classification	0.807	2	0.668	0.810 $\pm$ 0.053	0.707–0.913	<0.001

Subsequent Hospital Mortality Predicted on the First Day of Extracorporeal Membrane Oxygenation Support

Predictive Factors	Cutoff Point	Youden Index	Sensitivity (%)	Specificity (%)	Overall Correctness (%)	PPV (%)	NPV (%)
APACHE IV	49[a]	0.78	81	97	89	96	84
APACHE III	91[a]	0.75	85	90	88	89	86
APACHE II	22[a]	0.66	79	88	84	87	81
SOFA	13[a]	0.56	72	84	78	82	75
RIFLE category	Non-ARF	0.44	96	48	72	65	92
	R-category[a]	0.49	87	61	74	69	82
	I-category	0.46	62	84	73	79	69
	F-category	0	0	100	50	100	50

APACHE: Acute Physiology And Chronic Health Evaluation

Evaluation of Outcome Scoring Systems for Patients on Extracorporeal Membrane Oxygenation

Age (ans)	
Temperature (°C)	37
MAP (mmHg)	70
HR (/min)	80
RR (/min)	15
Mecanical Ventilation	○ No ○ Yes
FiO2 (%)	
pO2 (mmHg)	90
pCO2 (mmHg)	40
Arterial pH	7.4
Na+ (mEq/L)	140
Urine Output (mL/24h)	
Creatinine (mg/dL)	1
Urea (mEq/L)	4
BSL (mg/dL)	100
Albumin (g/L)	40
Bilirubin (mg/dL)	1
Ht (%)	40
WBC (x1000/mm3)	10
GCS :	☐ Not available
- Eyes	4. Spontaneous
- Verbal	5. Oriented
- Motor	6. On Command

Chronic Health Condition :
- ☐ CRF / HD
- ☐ Cirrhosis
- ☐ Hepatic Failure
- ☐ Metastatic Carcinoma
- ☐ Lymphoma
- ☐ Leukemia / Myeloma
- ☐ Immunosuppression
- ☐ AIDS

Admission Information :
- Pre-ICU LOS (days) [ ]
- Origin: Other
- Readmission: ◉ No ○ Yes
- Emergency Surgery: ◉ No ○ Yes

Admission Diagnosis :
- ○ Non operative ○ Postoperative
- System
- Diagnosis
- Thrombolysis : ◉ No ○ Yes

[Calculate]

APACHE IV Score		/286
APS Score		/239
Estimated Mortality Rate		%
Estimated Length of Stay		days

APACHE IV mortality rate ≤ 49%

Mortality rate Cutoff 49%

P < 0.001

APACHE IV mortality rate > 49%

Cumulative Survival vs Days
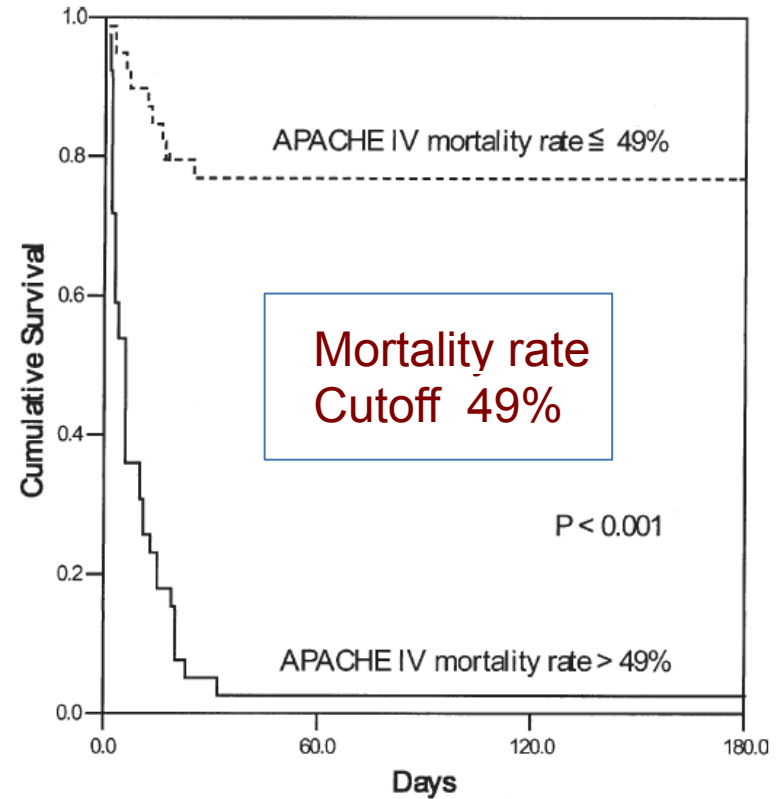
HTx Udine Experience
2005 – 2015

Recipient		ECMO	NON ECMO
N°. of patients		27	220

APACHE IV score

Patients were stratificated the day before heart transplantation

Exclusion criteria

- VADs
- Amyloidosis
- Needing kidney-HTx

HTx Udine Experience 2005 – 2015 | APACHE IV score

Recipient		ECMO	NON ECMO	P Value
N°. of patients		27	220	-
Female, n. (%)		3 (11)	35 (16)	ns
Age (years), mean ± sd		52.1±10	56.4±11	ns
Crea (mg/dl), mean ± sd		1.73±0.6	1.39±0.6	0.005
Redo, n. (%)		11 (40)	70 (32)	ns
DM, n. (%)		4 (15)	62 (28)	ns
IABP		24 (89)	8 (4)	<0.001
Inotropi		22 (82)	38 (17)	<0.001
	Disease			
	Post-ischemic, n. (%)	15 (56)	99 (45)	ns
	Dilatative, n. (%)	8 (29)	82 (37)	ns
	Other, n. (%)	4 (15)	39 (18)	ns

HTx Udine Experience
2005 – 2015

Donor		ECMO	NON ECMO	P Value
Age (years), mean ± sd		52.1±10	56.4±11	ns
Female, n. (%)		6 (22)	87 (39)	ns
Utilisation of more than 1 inotrope or more than low dosage of one, n. (%)		3 (11)	32 (15)	ns
Coltural positivity, n. (%)		7 (3)	35 (16)	ns
Coronaropathy, n. (%)		5 (18)	39 (18)	ns
Pt studied, n. (%)		16 (59)	128 (88)	ns
Ischemic time (min), mean ± sd		**220±63**	**192±59**	**0.028**
	Cause of death			
	Vascular, n. (%)	13 (48)	114 (41)	ns
	Trauma, n. (%)	10 (37)	78 (35)	ns
	Other, n. (%)	4 (15)	28 (13)	ns

Results

	ECMO	NON ECMO	P Value
Mean F-U (years)	**3.0 ± 2.7**	**5.9 ± 3.0**	-
Mean ECMO time (days)	**9.4 ± 12**	-	-
Hemodialysis (%)	22.2	6.4	0.01
Mechanical ventilation (h), mean ± sd	87±36	47±69	<0.01
ICU stay (days), mean ± sd	10.7±6	8±6	<0.01
Hospital stay (days), mean ± sd	49.4±51	32.3±24	<0.01
Re-exploration for bleeding (%)	33	15	0.03
30 Days mortality (%)	**22.2**	**5.5**	**<0.01**

Early mortality in ECMO group →

CAUSE OF DEATH

5 pts sepsis/MOF
2 pts graft failure
1 pt hyperacute rejection

Long-term survival

Survival Functions

$P < 0.01$

- NE group
- E group, APACHE IV < 47
- E group, APACHE IV = o > 47

Estimate survival (%)	1 year	3 years
NE group	91	83
ECMO Apache IV < 47	94	80
ECMO Apache IV ≥ 47	22	-

months

Cutoff score 47
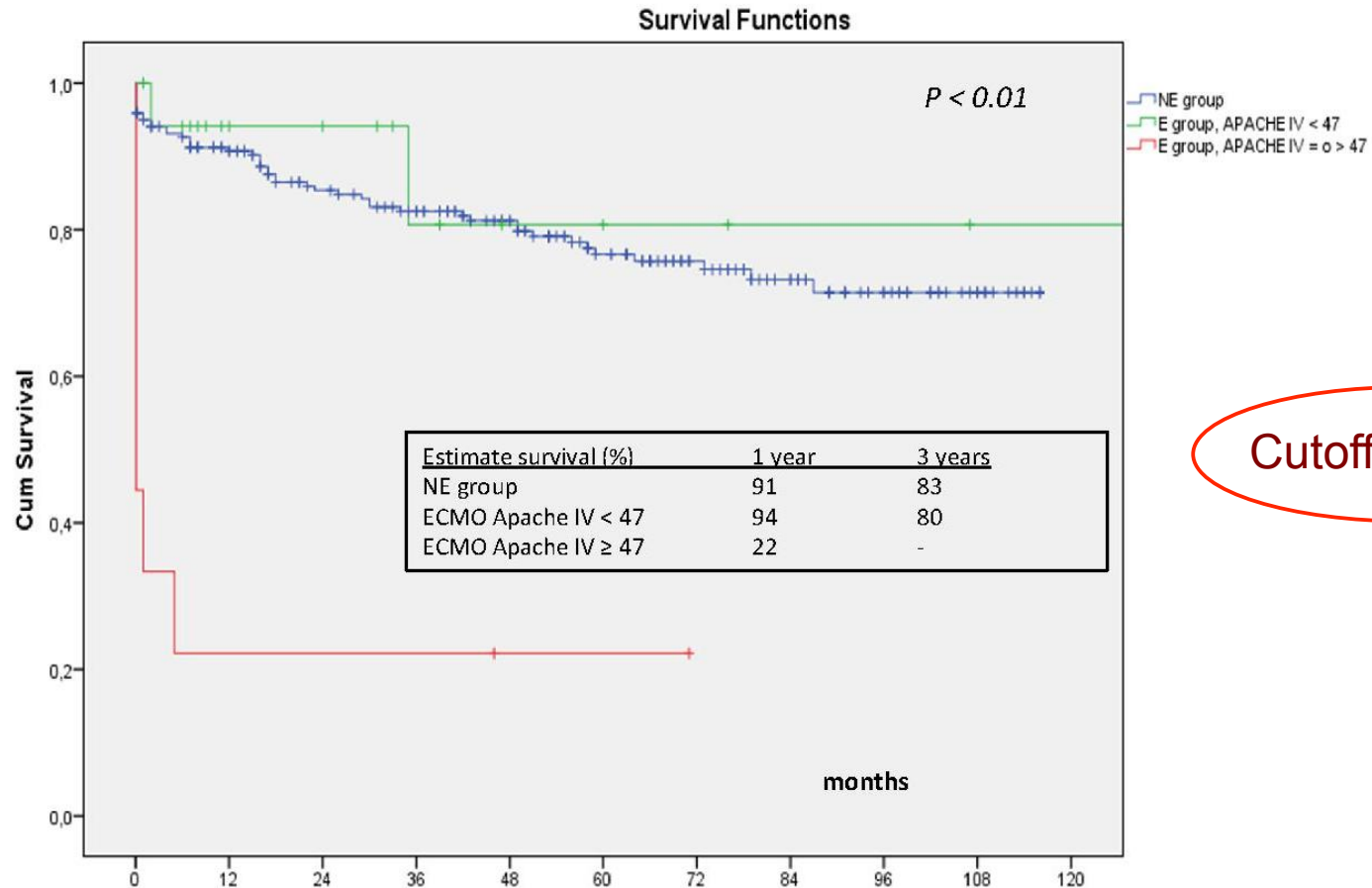
	0	12	24	36	48	60	72	84	96	108	120	
NE	220	182	153	140	118	89	66	53	31	13		
E Apache < 47	18	11	10	6	4	3	3	2	2	1		Patients at risk (n)
E Apache ≥ 47	9	2	2	2	1	1	0					

Conclusions

- ECMO as bridge to heart transplantation for unstable and unselected patients is associated with increased early mortality and morbidity.

- In our series these results seem not to be related to a single variable but to a global patient complexity with initial multiorgan failure.

- APACHE IV score seems to have a prognostic role in a such challenging patients. A cutoff value < 47 seems to predict the same outcome of standard recipients.

- In ECMO-patients with APACHE IV score > 47 could be reasonable identify a mid-term alternative cardiocirculatory support to better prepare the patient for the Htx (BiVAD, TAH).

Grazie

Cardiothoracic Department
University Hospital, S. Maria della Misericordia
Udine

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HTx Udine Experience 2005 – 2015

APACHE IV score

Recipient		ECMO	NON ECMO	P Value
N°. of patients		27	220	-
Female, n. (%)		3 (11)	35 (16)	ns
Age (years), mean ± sd		52.1±10	56.4±11	ns
Crea (mg/dl), mean ± sd		1.73±0.6	1.39±0.6	0.005
Redo, n. (%)		11 (40)	70 (32)	ns
DM, n. (%)		4 (15)	62 (28)	ns
IABP		24 (89)	8 (4)	<0.001
Inotropi		22 (82)	38 (17)	<0.001
	Disease			
	Post-ischemic, n. (%)	15 (56)	99 (45)	ns
	Dilatative, n. (%)	8 (29)	82 (37)	ns
	Other, n. (%)	4 (15)	39 (18)	ns

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Results

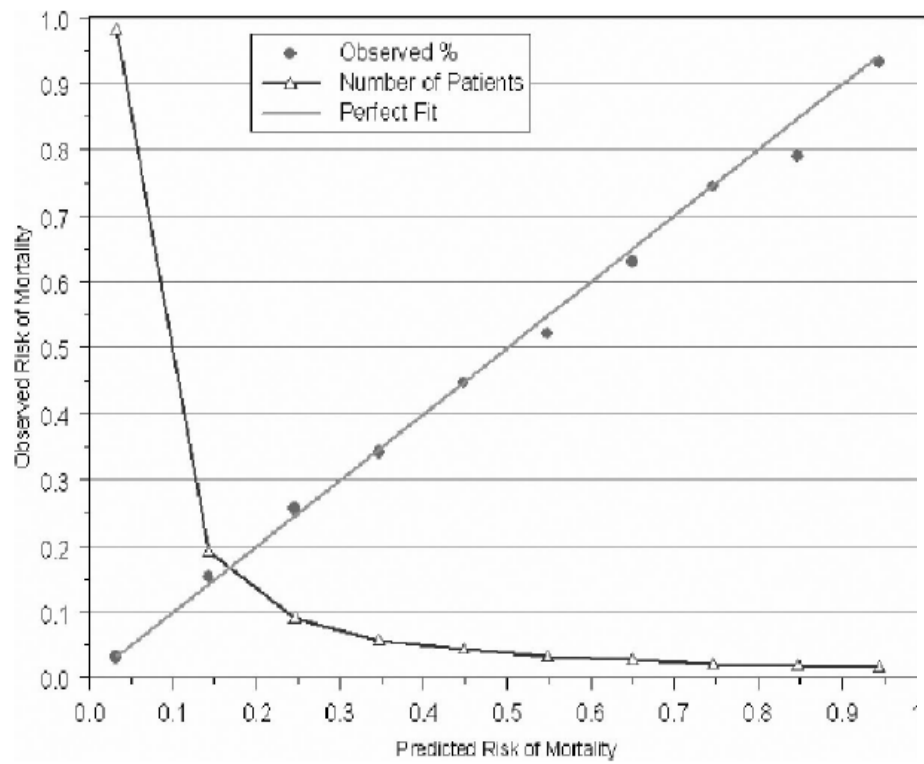|		ECMO	NON ECMO	P Value
Mean F-U (years)		**3.0 ± 2.7**	**5.9 ± 3.0**	-
Mean ECMO time (days)		**9.4 ± 12**	-	-
Hemodialysis (%)		22.2	6.4	0.01
Mechanical ventilation (h), mean ± sd		87±36	47±69	<0.01
ICU stay (days), mean ± sd		10.7±6	8±6	<0.01
Hospital stay (days), mean ± sd		49.4±51	32.3±24	<0.01
Re-exploration for bleeding (%)		33	15	0.03
30 Days mortality (%)		**22.2**	**5.5**	**<0.01**

Early mortality in ECMO group

CAUSE OF DEATH

5 pts sepsis/MOF
2 pts graft failure
1 pt   hyperacute rejection

Acute Physiology and Chronic Health Evaluation (APACHE) IV: Hospital mortality assessment for today's critically ill patients*

Jack E. Zimmerman, MD, FCCM; Andrew A. Kramer, PhD; Douglas S. McNair, MD, PhD;

Age	Continuous Measure Plus Five Spline Terms
APS variables	Weight determined by most abnormal value within first APACHE day; sum of weights equals the APS, which ranges from 0 to 252. Five spline terms added. Variables include pulse rate, mean blood pressure, temperature, respiratory rate, PaO_2/FIO_2 ratio (or $P(A-a)O_2$ for intubated patients with $FIO_2 \geq 0.5$), hematocrit, white blood cell count, creatinine, urine output, blood urea nitrogen, sodium, albumin, bilirubin, glucose, acid base abnormalities, and neurological abnormalities based on Glasgow Coma Score
Chronic health variables	AIDS, cirrhosis, hepatic failure, immunosupression, lymphoma, leukemia or myeloma, metastatic tumor. Not used for elective surgery patients
ICU admission diagnosis	116 categories (see Appendix Tables 1 and 2)
ICU admission source	Floor, emergency room, operating/recovery room, stepdown unit, direct admission, other ICU, other hospital, other admission source
Length of stay before ICU admission	Square root plus four spline terms
Emergency surgery	Y/N
Unable to assess Glasgow Coma Scale score	Y/N
Thrombolytic therapy	For patients with acute myocardial infarction (Y/N)
Glasgow Coma Scale score rescaled	15 minus measured Glasgow Coma Scale score
PaO_2/FIO_2 ratio	
Mechanical ventilation	Y/N

Exclusion criteria
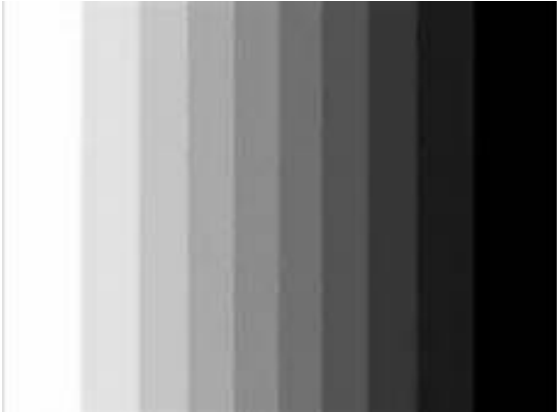
VADs
Amyloidosis
Needing kidney-HTx

APACHE IV score

Patients were stratificated the day before heart transplantation

VA ECMO patients should be considered a homogeneous population?

- For patients who do not recover cardiac function, clinical status may be very different among them.

-

-

- In this situation, an inadequate patient selection for HTx could lead to poor outcomes.

- Taking into account the shortage of donors, careful consideration when listing a patient in VA ECMO for HTx.

Is there a model to predict outcome?

- A recognised risk score model to predict mortality after bridged Htx on VA ECMO is still lacking.

-

- From literature, only non-uniform, single-institute-derived parameters have been associated with mortality during ECMO support or after weaning from it.

OUR STUDY

We aimed to verify if the APACHE IV score is able to predict survival in patients who underwent heart transplantation supported by ECMO.

Our study

- Tabella pz

Our study

- Tabella comorbidities

conclusions

- We ....

Who are the patients requiring ECMO

- VA ECMO represents a salvage procedure for unselected and heterogeneous population of INERMACS 1 and 2 or sustaining cardiac arrest patients.
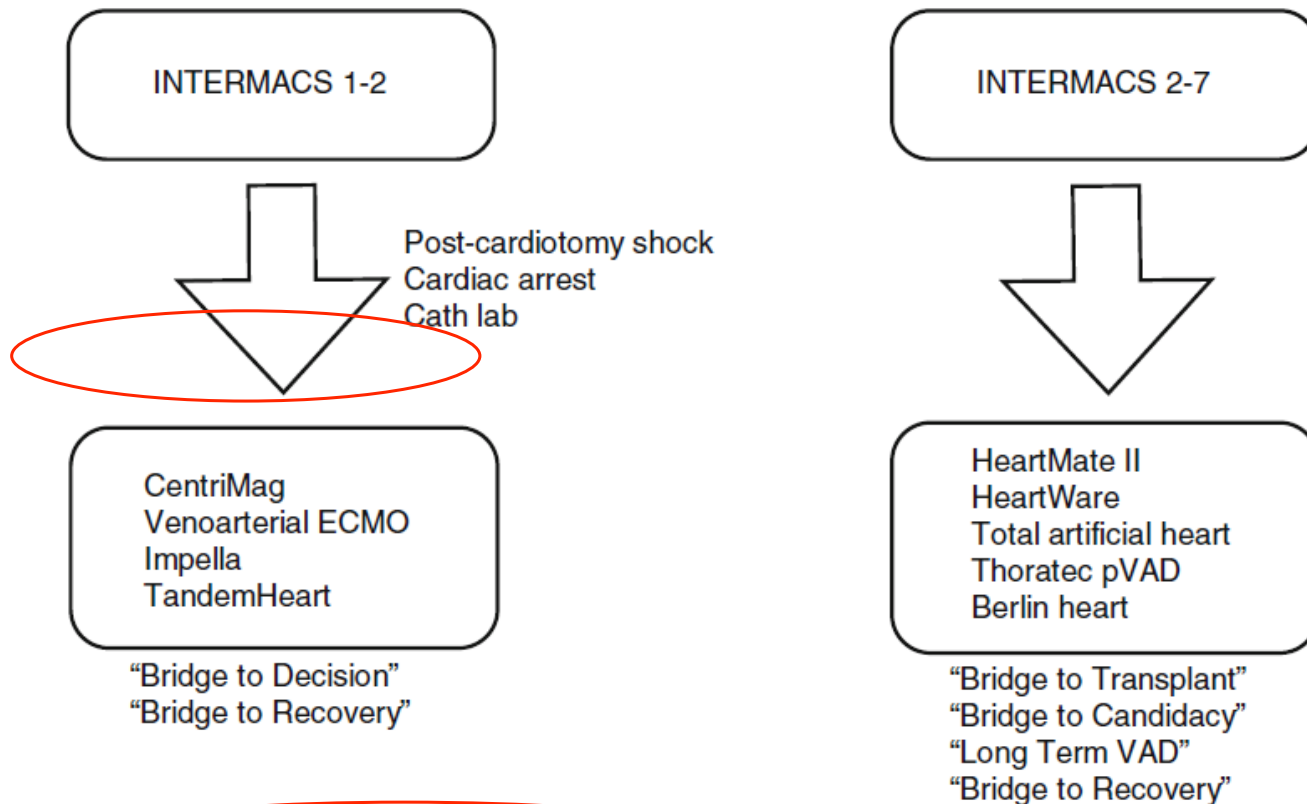
Table 5. INTERMACS profile descriptions.

Profile 1: Critical cardiogenic shock. ("Crash and burn").
Profile 2: Progressive decline. ("Sliding on inotropes").
Profile 3: Stable but inotrope dependent. ("Dependent stability").
Profile 4: Resting symptoms.
Profile 5: Exertion intolerant.
Profile 6: Exertion limited.
Profile 7: Advanced NYHA III.

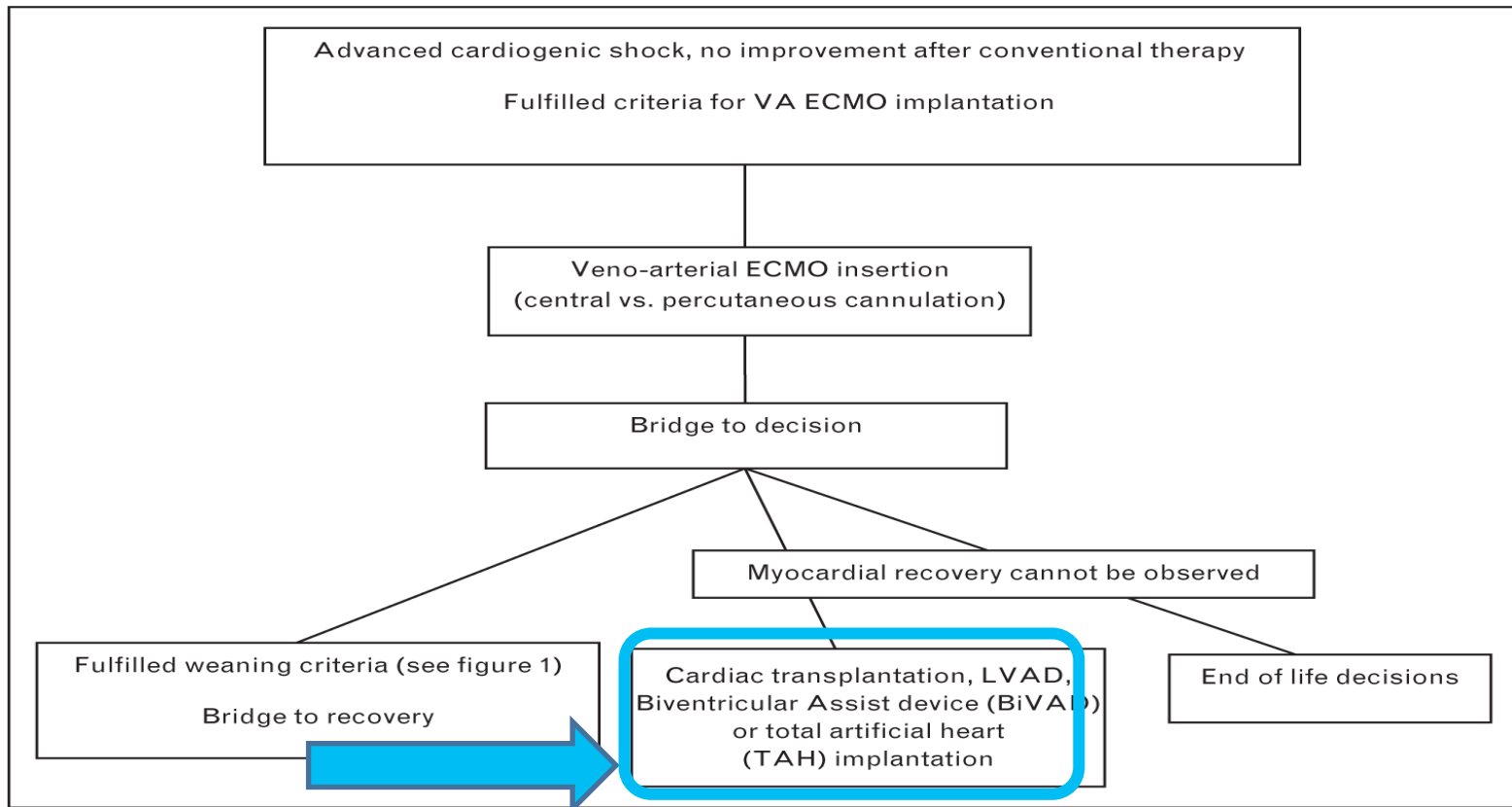# Treatment Options for End-Stage Cardiac Failure

Gurmeet Singh

```
┌─────────────────────┐                          ┌─────────────────────┐
│   INTERMACS 1-2     │                          │   INTERMACS 2-7     │
└─────────────────────┘                          └─────────────────────┘
           │                                                 │
           ▼         Post-cardiotomy shock                   ▼
                     Cardiac arrest
                     Cath lab
```

```
┌─────────────────────┐                          ┌─────────────────────┐
│  CentriMag          │                          │  HeartMate II       │
│  Venoarterial ECMO  │                          │  HeartWare          │
│  Impella            │                          │  Total artificial   │
│  TandemHeart        │                          │    heart            │
│                     │                          │  Thoratec pVAD      │
│                     │                          │  Berlin heart       │
└─────────────────────┘                          └─────────────────────┘
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"Bridge to Decision"   "Bridge to Transplant"
"Bridge to Recovery"   "Bridge to Candidacy"
                                                 "Long Term VAD"
                                                 "Bridge to Recovery"

1	Critical cardiogenic shock
2	Progressive decline on inotropes
3	Stable, but inotrope dependent
4	Symptoms at rest; home on oral therapy
5	Exertion intolerant
6	Exertion limited
7	Advanced NYHA class III symptoms

F. Sangalli et al. (eds.), *ECMO-Extracorporeal Life Support in Adults*

ECMO

Bridge to decision

Adult Heart Transplants
Kaplan-Meier Survival by VAD usage
(Transplants: January 1999 – June 2013)

All pair-wise comparisons with ECMO were significant at p < 0.05. Continuous flow vs. Pulsatile flow and No LVAD / Inotropes vs. Pulsatile flow were significant at p < 0.05. No other pair-wise comparisons were significant at p < 0.05.

Legend:
- Pulsatile flow (N=3,602)
- Continuous flow (N=3,703)
- ECMO (N=157)
- No LVAD / No Inotropes (N=11,042)
- No LVAD / Inotropes (N=11,446)

Survival (%)

Years