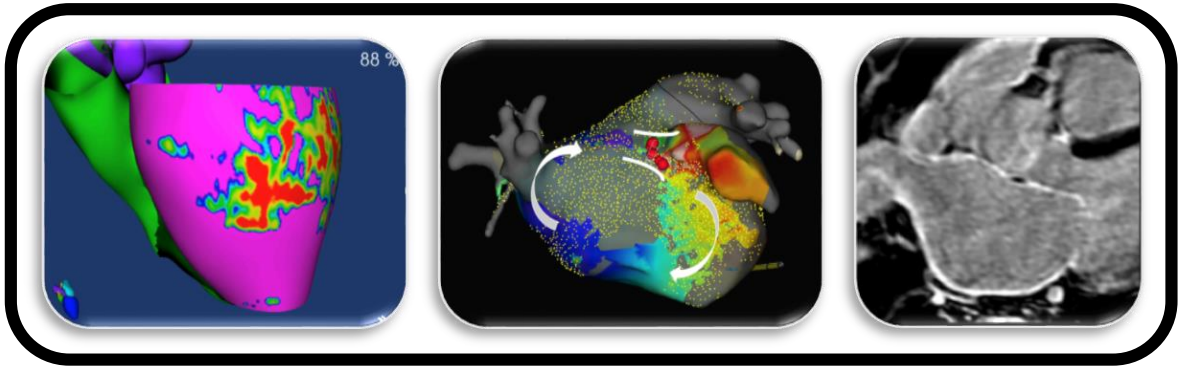
*UPDATE SCD 2025

profid-project.eu

VT ablation in terminal heart failure



Philipp Sommer, FHRS, FESC, FEHRA
Department of Electrophysiology and Rhythmology
Heart- and Diabetescenter NRW Bad Oeynhausen
EiC EHJ Case Reports

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Disclosures:

Honoraria *(not personal)* by

- Abbott, J&J MedTec, Biotronik, Boston Scientific, Medtronic, Zoll
- Siemens Healthcare
- Boehringer Ingelheim/Bayer/Pfizer/BMS, Daiichi Sankyo.

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- Boehringer Ingelheim, Daiichi Sankyo

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- Abbott, Boston Scientific, CVRx
- Imricor

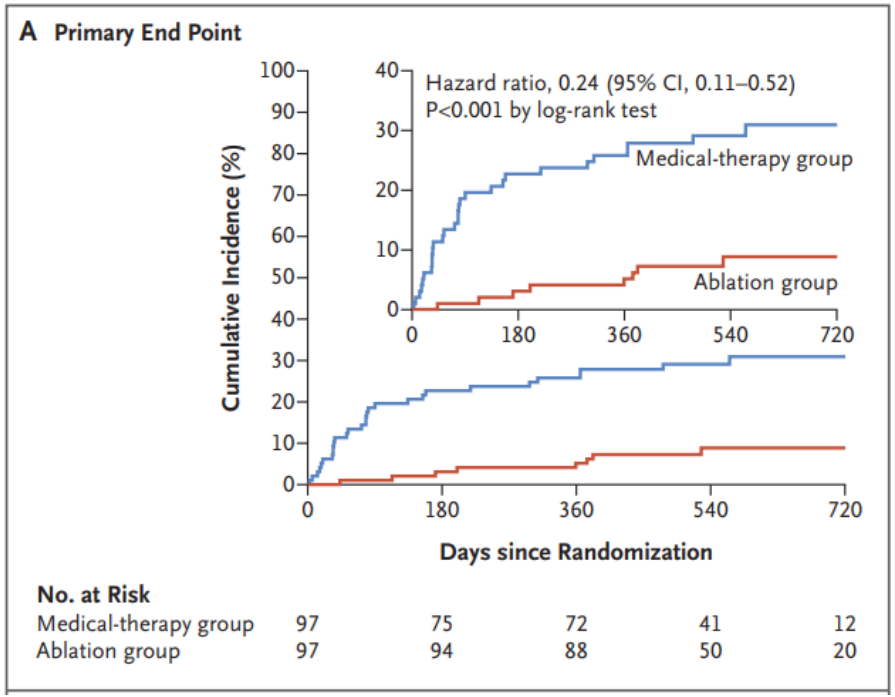
… The CASTLE story….

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Catheter Ablation in End-Stage Heart Failure with Atrial Fibrillation

Christian Sohns, M.D., Henrik Fox, M.D., Nassir F. Marrouche, M.D., Harry J.G.M. Crijns, M.D., Ph.D., Angelika Costard-Jaeckle, M.D., Leonard Bergau, M.D., Gerhard Hindricks, M.D., Nikolaos Dagres, M.D., Samuel Sossalla, M.D., Rene Schramm, M.D., Ph.D., Thomas Fink, M.D., Mustapha El Hamriti, M.D., Maximilian Moersdorf, M.D., Vanessa Sciacca, M.D., Frank Konietschke, Ph.D., Volker Rudolph, M.D., Jan Gummert, M.D., Jan G.P. Tijssen, Ph.D., and Philipp Sommer, M.D., for the CASTLE HTx Investigators

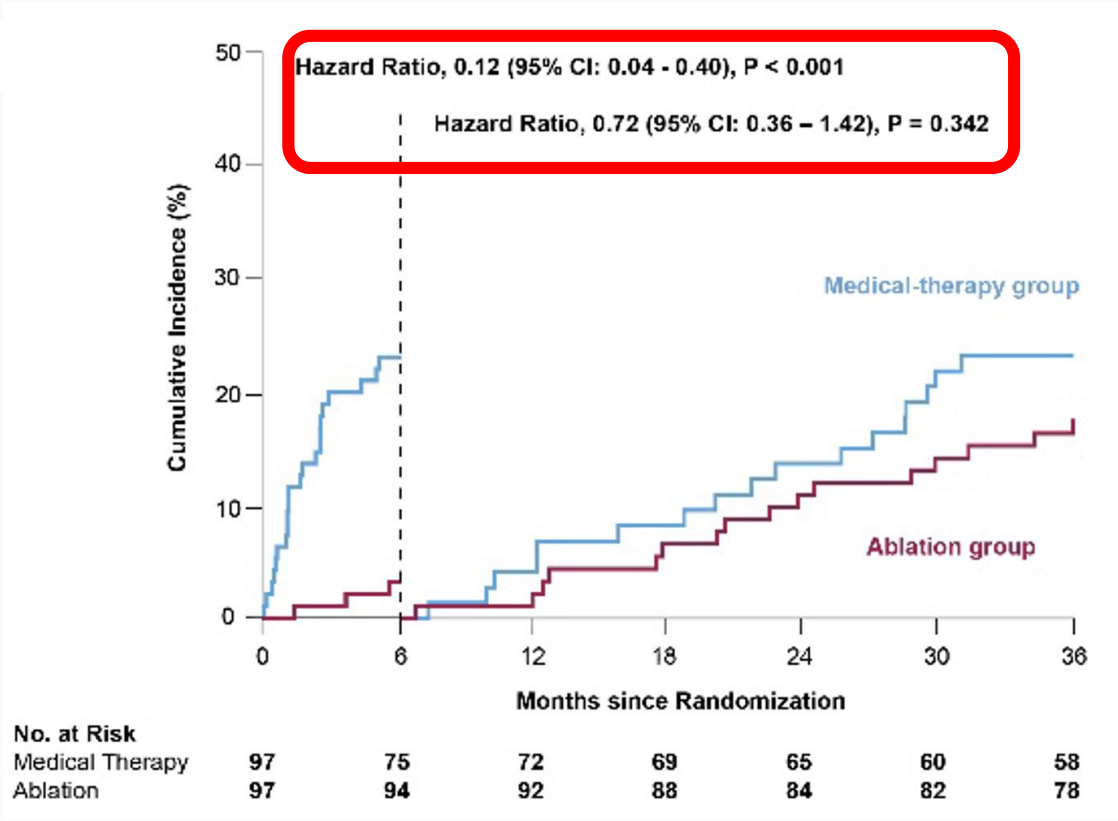


Sohns C et al. N Engl J Med 2023

Primary End Point over Time

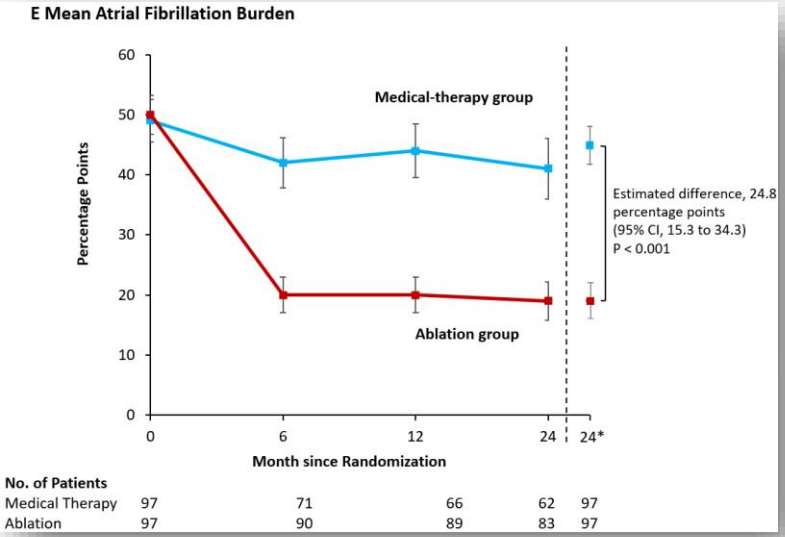
Circulation

3-Year Outcomes of Catheter Ablation in Patients with End-Stage Heart Failure and Atrial Fibrillation



Sohns, Sommer. Circulation 2025, Aug 31

Ablation in HF: reverse remodelling



Sohns, Sommer. Circulation 2024

Sciacca, Sommer. EHJ HJ 10/2024

Background: Cardiovasular death in CASTLE-HTx

Table 2. Primary and Secondary End Points.

End Point	Ablation Group (N=97)	Medical-Therapy Group (N=97)	Hazard Ratio (95% CI)*	P Value†
	no. (%)			
Primary end point‡	8 (8)	29 (30)	0.24 (0.11 to 0.52)	<0.001
Secondary end points				
Death from any cause	6 (6)	19 (20)	0.29 (0.12 to 0.72)	**0.005**
Cardiovascular	5 (5)	18 (19)	0.25 (0.09 to 0.68)	
Cerebrovascular	0	1 (1)		
Cancer	1 (1)	0		
Death after nonfatal primary end point	0	5 (5)		
Implantation of left ventricular assist device	1 (1)	10 (10)	0.09 (0.01 to 0.70)	**0.004**
Urgent heart transplantation	1 (1)	6 (6)	0.15 (0.02 to 1.25)	

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Rationale for CASTLE VT

- **Timely referrals** for HTx and LVAD play a key role in favorable outcomes in patients with advanced (HF)
- Cardiovascular mortality, driven by **sudden cardiac death**, is the main mortality reason on the waiting list for heart transplantation.
- Many of the sudden deaths in clinical trials are **not prevented** by an ICD
- VT ablation is an **established treatment option** in the management of patients with ICM and ventricular arrhythmias
- The role of **VT ablation** in patients with advanced HF is unknown

Background: Proportion of deaths in HF Trials

Figure 1. Number of Deaths by Adjudicated Cause and Ejection Fraction Category for Pooled DAPA-HF and DELIVER Populations

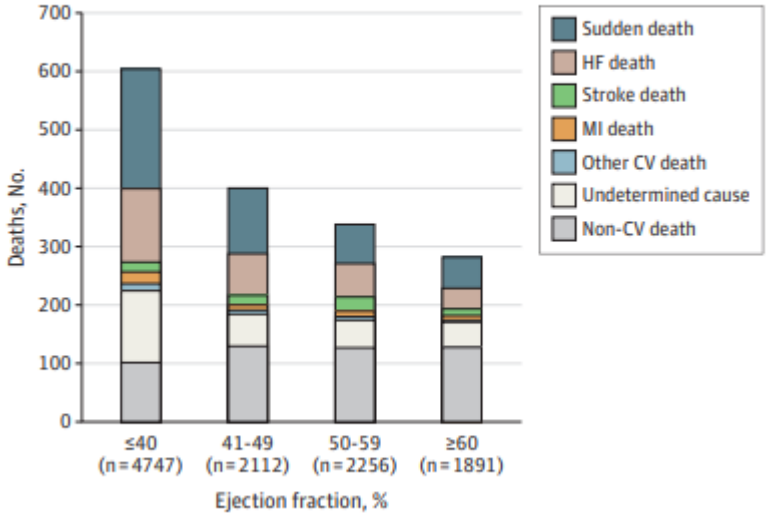


Table 2. Incidence and Proportion of Deaths by Cause According to EF at Baseline Among Patients Who Died, Pooled DAPA-HF and DELIVER Populations (N = 11 007)

	EF ≤40% (n = 4747)		EF ≤49% (n = 2112)		EF 50%-59% (n = 2256)		EF ≥60% (n = 1891)		*P* value	
Cause of death	No. (% of deaths)	Rate/100 PY	No. (% of deaths)	Rate/ 100 PY	No. (% of deaths)	Rate/ 100 PY	No. (% of deaths)	Rate/ 100 PY	Proportions	Incidence rates
Total deaths	605 (100)	8.8	401 (100)	8.8	339 (100)	6.7	283 (100)	6.7	NA	<.001
CV death	380 (62.8)	5.6	216 (53.9)	4.7	164 (48.4)	3.2	112 (39.6)	2.7	<.001	<.001
HF	125 (20.7)	1.8	71 (17.7)	1.6	57 (16.8)	1.1	36 (12.7)	0.9	<.001	<.001
Sudden death	206 (34.0)	3.0	113 (28.2)	2.5	68 (20.1)	1.3	54 (19.1)	1.3	<.001	<.001
Stroke	17 (2.8)	0.2	17 (4.2)	0.4	24 (7.1)	0.5	11 (3.9)	0.3	.71	.46
MI	20 (3.3)	0.3	9 (2.2)	0.2	10 (2.9)	0.2	8 (2.8)	0.2	.12	.25
Other CV	12 (2.0)	0.2	6 (1.5)	0.1	5 (1.5)	0.1	3 (1.1)	0.1	.30	.06
Non-CV	102 (16.9)	1.5	130 (32.4)	2.9	127 (37.5)	2.5	128 (45.2)	3.0	<.001	.001
Unknown	123 (20.3)	1.8	55 (13.7)	1.2	48 (14.2)	0.9	43 (15.2)	1.0	.02	<.001
Non-CV + unknown	225 (37.2)	3.3	185 (46.1)	4.1	175 (51.6)	3.4	171 (60.4)	4.0	<.001	.97
CV + unknown	503 (83.1)	7.3	271 (67.6)	6.0	212 (62.5)	4.2	155 (54.8)	3.7	<.001	<.001

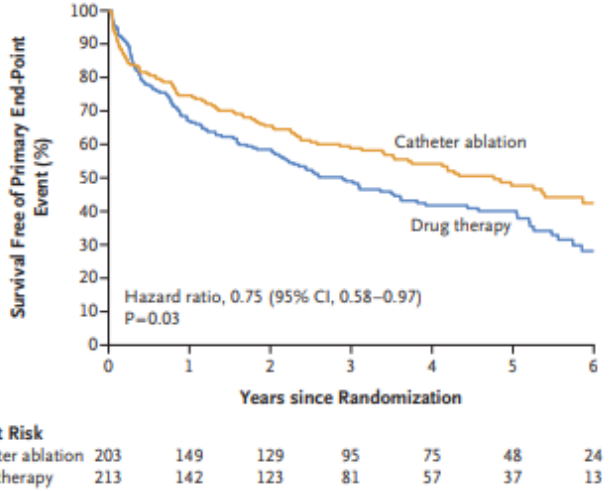
Background: Type of Death in VANISH2

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Catheter Ablation or Antiarrhythmic Drugs for Ventricular Tachycardia

J.L. Sapp, A.S.L. Tang, R. Parkash, W.G. Stevenson, J.S. Healey, L.J. Gula, G.M. Nair, V. Essebag, L. Rivard, J.-F. Roux, P.B. Nery, J.-F. Sarrazin, G. Amit, J.-M. Raymond, M. Deyell, C. Lane, F. Sacher, C. de Chillou, V. Kuriachan, A. AbdelWahab, I. Nault, K. Dyrda, S. Wilton, U. Jolly, A. Kanagasundram, and G.A. Wells, for the VANISH2 Study Team*



Outcome	Ablation N=203	AAD N=213	Hazard Ratio (95% CI)
Components of the Primary Outcome			
Death	45 (22.2%)	54 (25.4%)	0.84 (0.56,1.24)
From cardiovascular causes	29 (14.3%)	25 (11.7%)	1.23 (0.72,2.10)
From non-cardiovascular causes	14 (6.9%)	26 (12.2%)	0.54 (0.28,1.03)
From unknown cause	2 (1.0%)	3 (1.4%)	0.67 (0.11,3.92)

Hypothesis

Prophylactic catheter ablation of arrhythmogenic ventricular scar tissue will reduce mortality, need for LVAD implantation, and urgent heart transplantation in patients with end-stage heart failure related to ischemic cardiomyopathy.

Trial design

- **Single center, open-label, investigator-initiated**
- **Randomized (160 pts; 1:1 ablation vs medical therapy)**
- **Superiority of ablation vs medical therapy in terms of**
  - A composite of death from any cause, LVAD implantation, or urgent HTx *(Primary end-point)*
  - Death from any cause *(Secondary end-point)*
- **Duration of follow-up:** approximately 2 years

Sohns C, Sommer P et al. EJHF 2024

Main inclusion & exclusion criteria

Inclusion criteria

(1) Ischaemic cardiomyopathy with left ventricular ejection fraction ≤35% (measured in the last 6 weeks prior to enrolment)

(2) Eligible for heart transplantation due to end-stage heart failure

(3) New York Heart Association class ≥ III

(4) Impaired functional capacity or inability to exercise

(5) Indication for ICD therapy due to primary prevention

(6) Implanted ICD or ICD implantation within 3 months after randomization

(7) The patient is willing and able to comply with the protocol and has provided written informed consent

(8) Age ≥18 years

Exclusion criteria

(1) Previous catheter ablation for ventricular arrhythmias

(2) Previous appropriate ICD therapy for ventricular arrhythmias

(3) Acute coronary syndrome, cardiac surgery, angioplasty, or cerebrovascular accident within 4 weeks prior to enrolment

(4) Untreated hypothyroidism or hyperthyroidism

(5) Woman currently pregnant, breastfeeding, or not using reliable contraceptive measures during fertility age

(6) Mental or physical inability to participate in the study

(7) Listed as 'high urgent' for heart transplantation

(8) Cardiac assist device implanted

(9) Planned cardiovascular intervention

(10) Life expectancy ≤12 month

(11) Uncontrolled hypertension

(12) Requirement for dialysis due to end-stage renal failure

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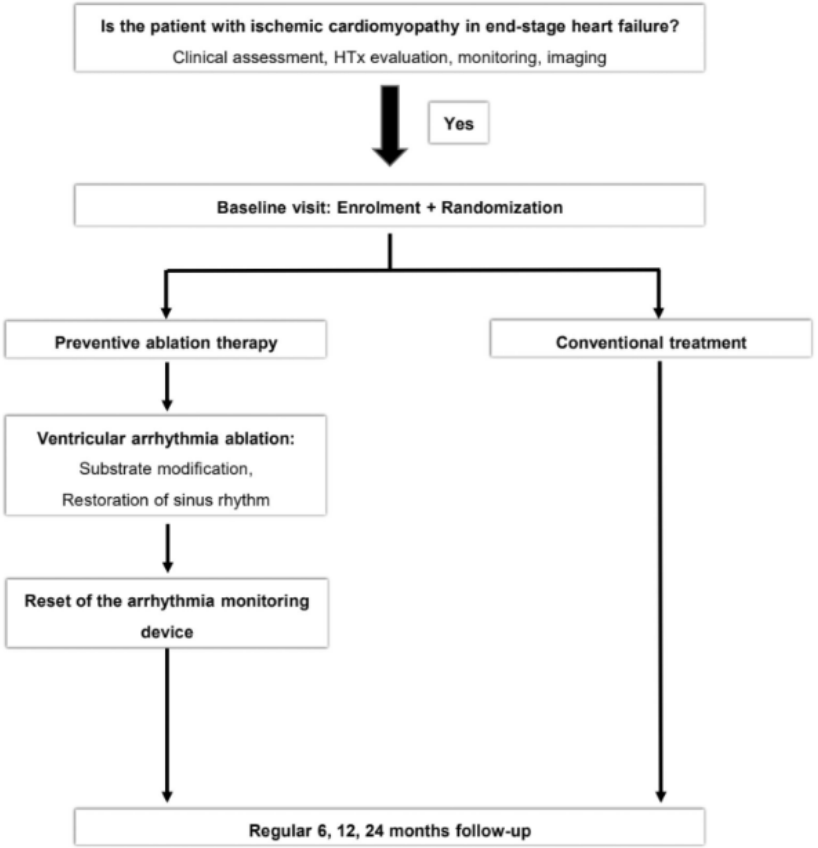
Treatment

VT Ablation

- **Programmed ventricular stimulation**
- **When VT induced: Activation mapping**
- **Scar related to ICM will be delineated (Ultra HD Mapping)**
- **Substrate Ablation**

Conventional

- **ESC guideline for the diagnosis and treatment of acute and chronic HF and its focused update**
- **ESC guidelines for the management of patients with VAs and the prevention of SCD**



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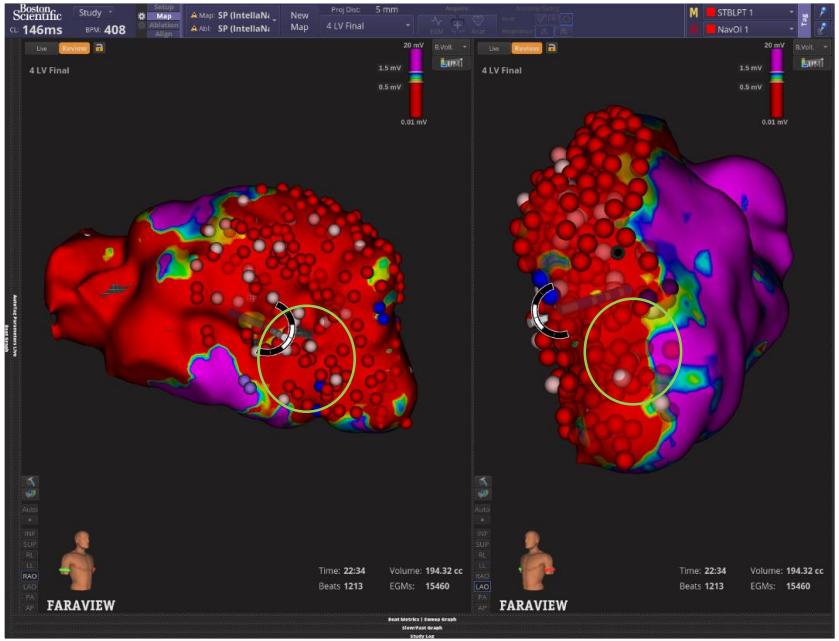
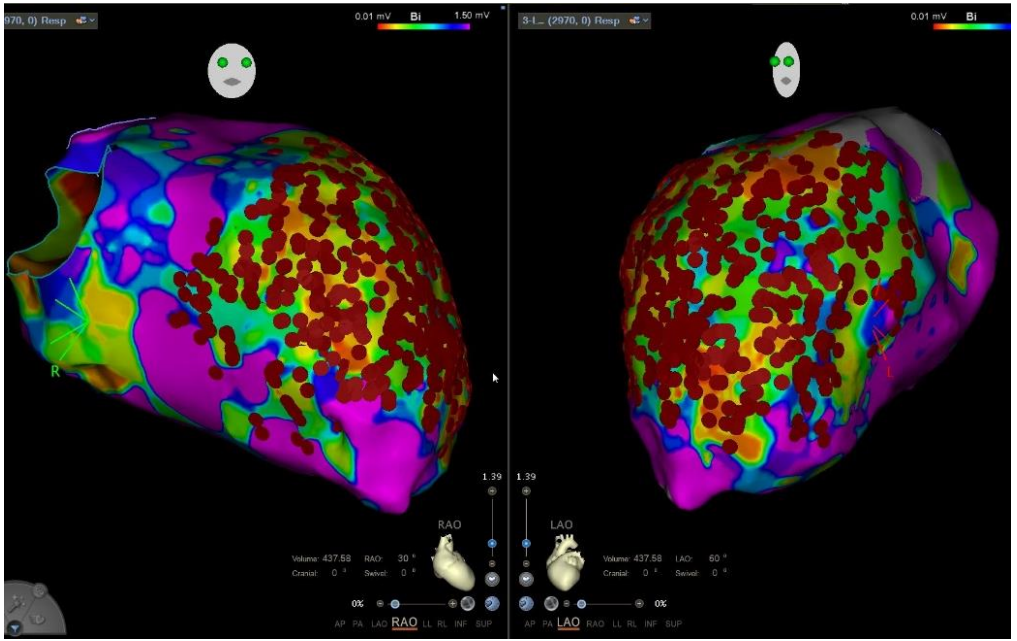
CASTLE – VT: Ablation Approach





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The *CASTLE-VT* trial is supported by an unrestricted research grant from Boston Scientific

Timeline

IRB approval: ✔ **June 2024**

ClinicalTrials.gov registration: ✔ **June 2024; NCT06556485**

Study design manuscript: ✔ **European Journal of Heart Failure 2024**

Status: Recruiting; ✔ **78 patients randomized since September 2024**

First scheduled interim analysis after patient #80

CASTLE-VT: Trial design manuscript

ESC European Society of Cardiology

European Journal of Heart Failure (2024)
doi:10.1002/ejhf.3512

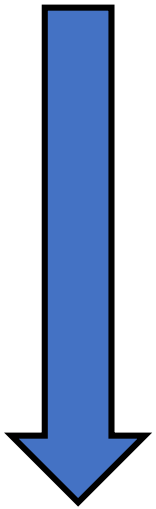
STUDY DESIGN

Preventive catheter ablation for ventricular arrhythmias in patients with end-stage heart failure referred for heart transplantation evaluation: Rationale for and design of the CASTLE-VT trial

Christian Sohns[1]*, Thomas Fink[1], Harry J.G.M. Crijns[2], Angelika Costard-Jaeckle[3,4], Nassir F. Marrouche[5], Samuel Sossalla[6,7], Rene Schramm[3,4], Mustapha El Hamriti[1], Maximilian Moersdorf[1], Maxim Didenko[1], Martin Braun[1], Vanessa Sciacca[1], Frank Konietschke[8], Volker Rudolph[9], Jan Gummert[3], Jan G.P. Tijssen[10], and Philipp Sommer[1], for the CASTLE-VT Investigators

What will be the results- have a guess:

Preventive VT Ablation in pts with end-stage HF will…



a) … LVAD/HTX + mortality +

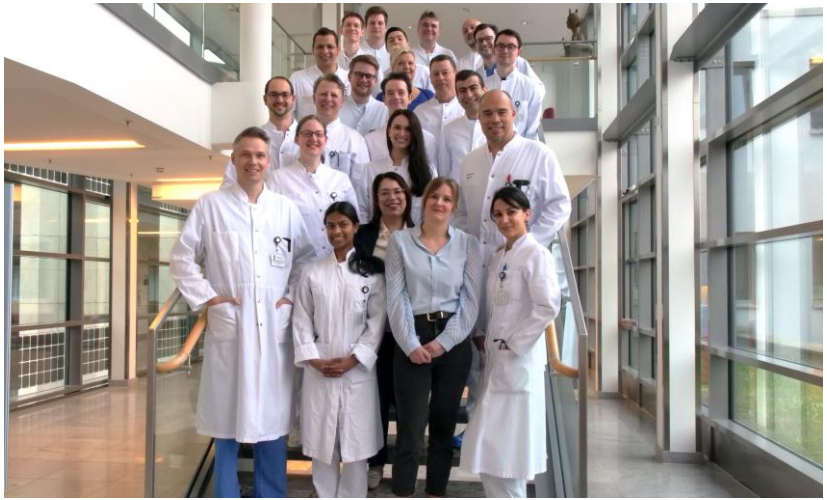
b) … LVAD/HTX + mortality -

c) … Only quality of life +

d) … no differences between the 2 groups

e) … harm the patients

Thank you!



psommer@hdz-nrw.de

Philipp Sommer

@Phiso_de

phiso_de

@phiso.bsky.social