

InEurHeart

Computed Tomography-Guided Catheter Ablation for Ventricular Tachycardia

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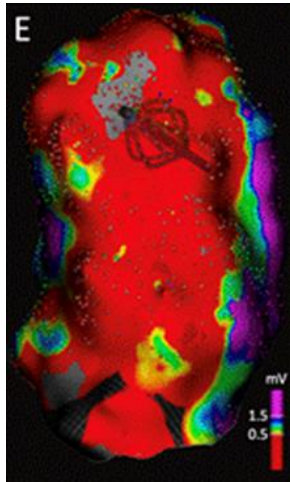
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VT ablation

Conventional VT ablation

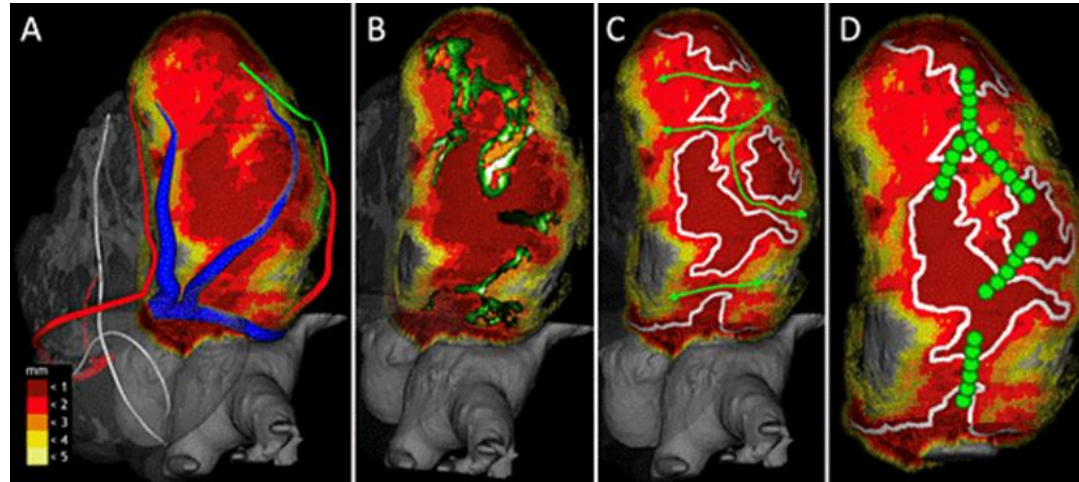
Identification of targets with invasive catheter mapping owing to operator experience



- No images
- Free to use any catheters/strategy
- Final endpoint > non-inducibility

CT-guided VT ablation

Identification of targets with non-invasively with CT-Scan and inHEART modelization



- Merging
- Ablation of isthmii identified by CT-Scan (40-50W with at least 10g & ≥ 45 sec)
- Inducibility when all isthmii have been targeted > if inducible > target the VT

▪ Main objective:

To compare conventional vs CT-guided VT ablation strategy in term of procedure duration, efficacy, safety and cost

Methods

Institutional multicentric, prospective, single-blinded randomized clinical trial,
Funded by EIT-Health.



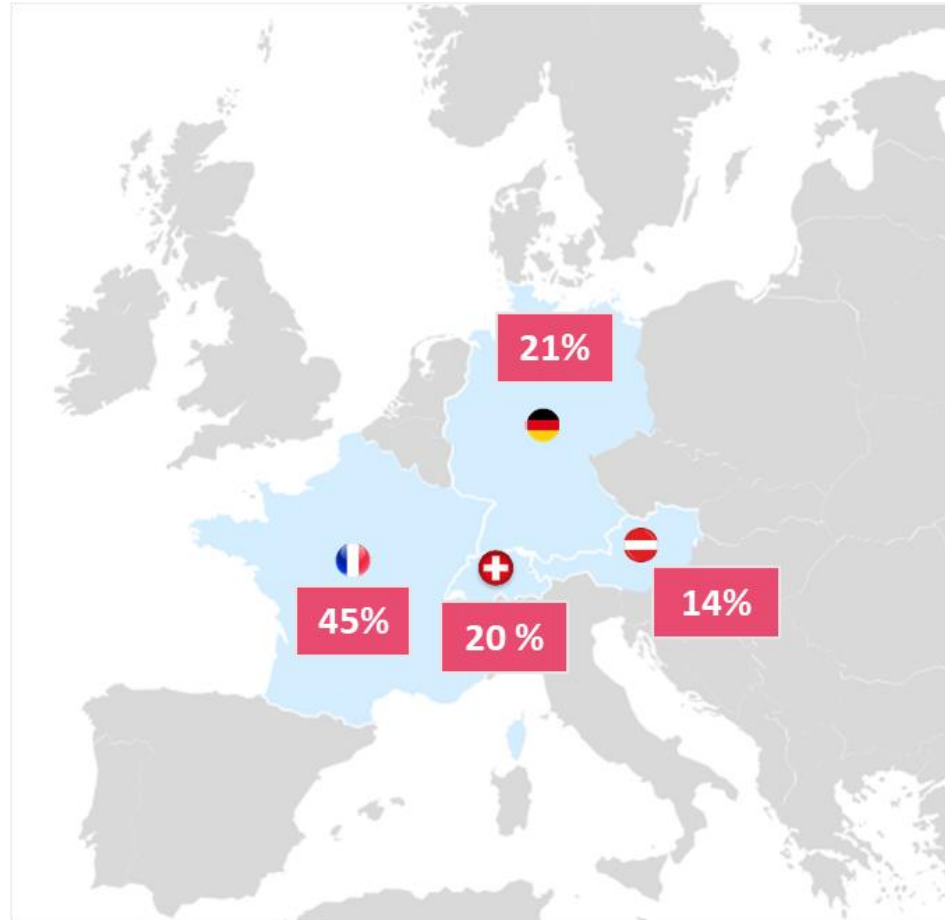
113 patients



14 Clinical sites



4 countries



France:

- ✓ Bordeaux University Hospital (Pr. Frédéric Sacher)
- ✓ Toulouse University Hospital (Pr. Philippe Maury)
- ✓ Clermont-Ferrand University Hospital (Dr. Grégoire Massoulié)
- ✓ Paris University Hospital (Dr. Xavier Waintraub)
- ✓ Limoges University Hospital (Dr. Benoît Guy-Moyat)

Germany:

- ✓ Rhön-Klinikum AG, Bad Neustadt (Pr. Thomas Deneke)
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- ✓ Technical University of Munich (TUM) (Pr. Isabel Deisenhofer)
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Austria:

- ✓ Medical University of Graz (Pr. Daniel Scherr)
- ✓ Ordensklinikum Linz GmbH (Pr. Dr. Helmut Pürerfellner)

Switzerland:

- ✓ Inselspital Bern (Pr. Tobias Reichlin)
- ✓ Vaudois University Hospital, Lausanne (Dr. Mathieu Le Bloa)

inEurHeart Workflow



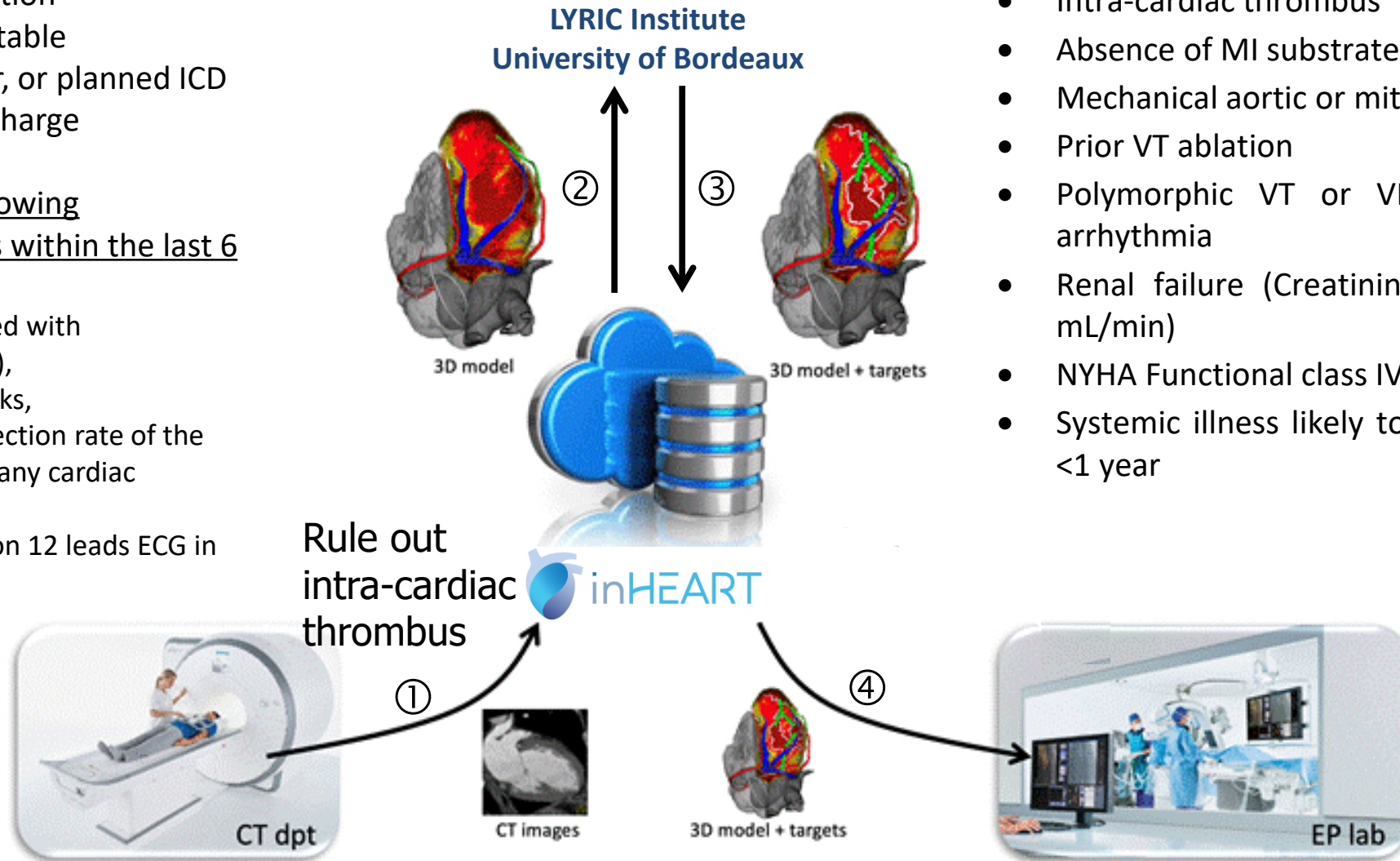
Inclusion criteria

- Indication for de-novo VT ablation
- Prior myocardial infarction
- Presence of an implantable cardioverter defibrillator, or planned ICD implantation before discharge
- And
- At least one of the following monomorphic VT events within the last 6 months:

A: ≥ 3 episodes of VT treated with antitachycardia pacing (ATP),
B: ≥ 1 appropriate ICD shocks,
C: sustained VT below detection rate of the ICD documented by ECG or any cardiac monitor,
D: Sustained VT recorded on 12 leads ECG in the absence of ICD

Exclusion criteria

- Active myocardial ischemia
- Intra-cardiac thrombus
- Absence of MI substrate
- Mechanical aortic or mitral valve
- Prior VT ablation
- Polymorphic VT or VF as presenting arrhythmia
- Renal failure (Creatinine clearance < 30 mL/min)
- NYHA Functional class IV heart failure
- Systemic illness likely to limit survival to < 1 year



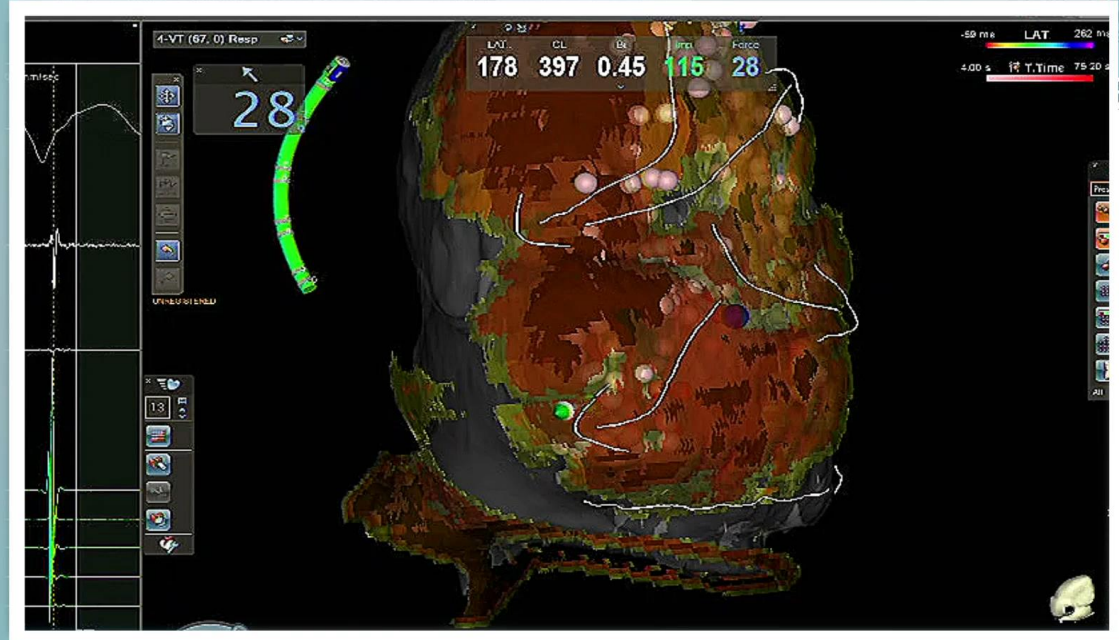
inEurHeart Workflow – CT guided arm



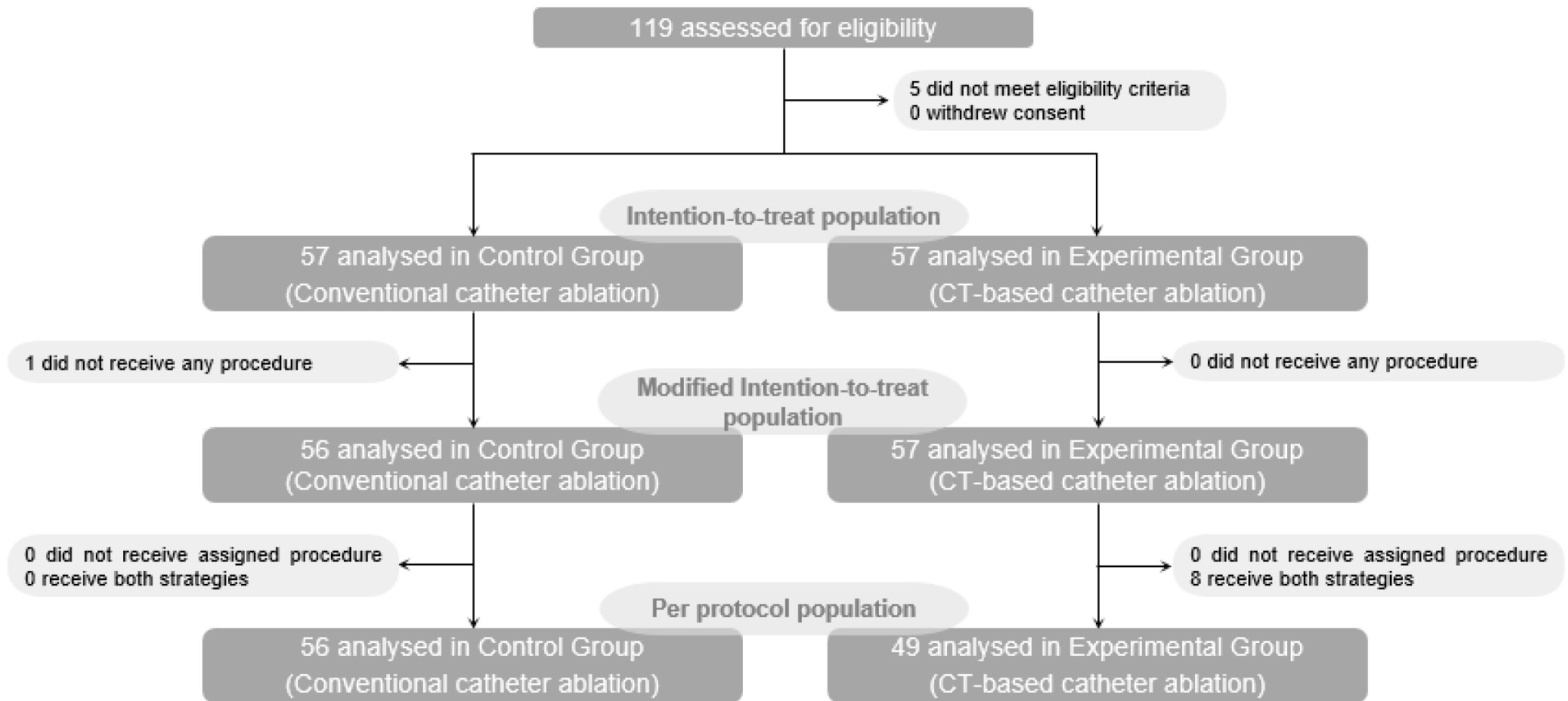
- Importing images
- Merging
- Ablation of the identified isthmus
- EP Study

If negative: stop there

If positive: map and ablate the induced VT



inEurHeart – Flowchart



inEurHeart – Baseline population



	Conventional VT ablation (n=56)	CT-guided VT ablation (n=57)
Age – years, mean $\pm$ SD	65.4 $\pm$ 9.1	63.8 $\pm$ 8.5
Male – no. (%)	50 (89.3)	53 (93.0)
BMI, mean $\pm$ SD	27.8 $\pm$ 4.0	29.6 $\pm$ 4.9
Diabetes– no. (%)	21 (39.6)	25 (43.9)
HTA - no. (%)	36 (67.9)	35 (61.4)
History of stroke/TIA – no. (%)	6 (11.3)	5 (8.8)
History of AF or A Flutter – no. (%)	12 (22.6)	14 (24.6)
CHADS-VASc risk score – mean, $\pm$ SD	3.4 $\pm$ 1.7	3.3 $\pm$ 1.2
Duration since myocardial infarction, months - mean, $\pm$ SD	183.6 $\pm$ 126.7	165.1 $\pm$ 125.8
Prior cardiac arrest – no. (%)	7 (13.2)	14 (24.6)
LVEF – %, mean, $\pm$ SD	34.5 $\pm$ 11.2	35.2 $\pm$ 11.4
History of electrical storm – no. (%)	23 (41.8)	21 (36.8)
Amiodarone use – no. (%)	31 (55.4)	35 (61.4)
Dysthyroidism – no. (%)	7 (13.2)	11 (19.3)

InEurHeart – Procedure



	Conventional VT ablation (n=56)	CT-guided VT ablation (n=57)
General anesthesia – no. (%)	21 (38.9)	21 (40.4)
Use of high density mapping catheter – no. (%)	51 (91.1)	14 (25.5)
Contact Force ablation catheter – no. (%)	51 (91.1)	52 (91.2)
Number of anatomical isthmus identified on CT– mean, $\pm$ SD	2.9 $\pm$ 1.3	3.2 $\pm$ 1.3
Non inducibility after CT ablation – no. (%)	NA	43 (75.4)
Any VT inducible at the end of the procedure – no. (%)	16 (33.3)	8 (17)
X-ray Duration (min)	12.8 $\pm$ 9.6	12.5 $\pm$ 13.1
Total RF duration – mean, $\pm$ SD	36.6 $\pm$ 19.5	44.4 $\pm$ 19.4
Major AE (grade 3 $\leq$) related to the procedure	2 (3.6)	1 (1.8)

InEurHeart – primary endpoint



Procedure duration definition:

Time between first catheter introduction to last RF application

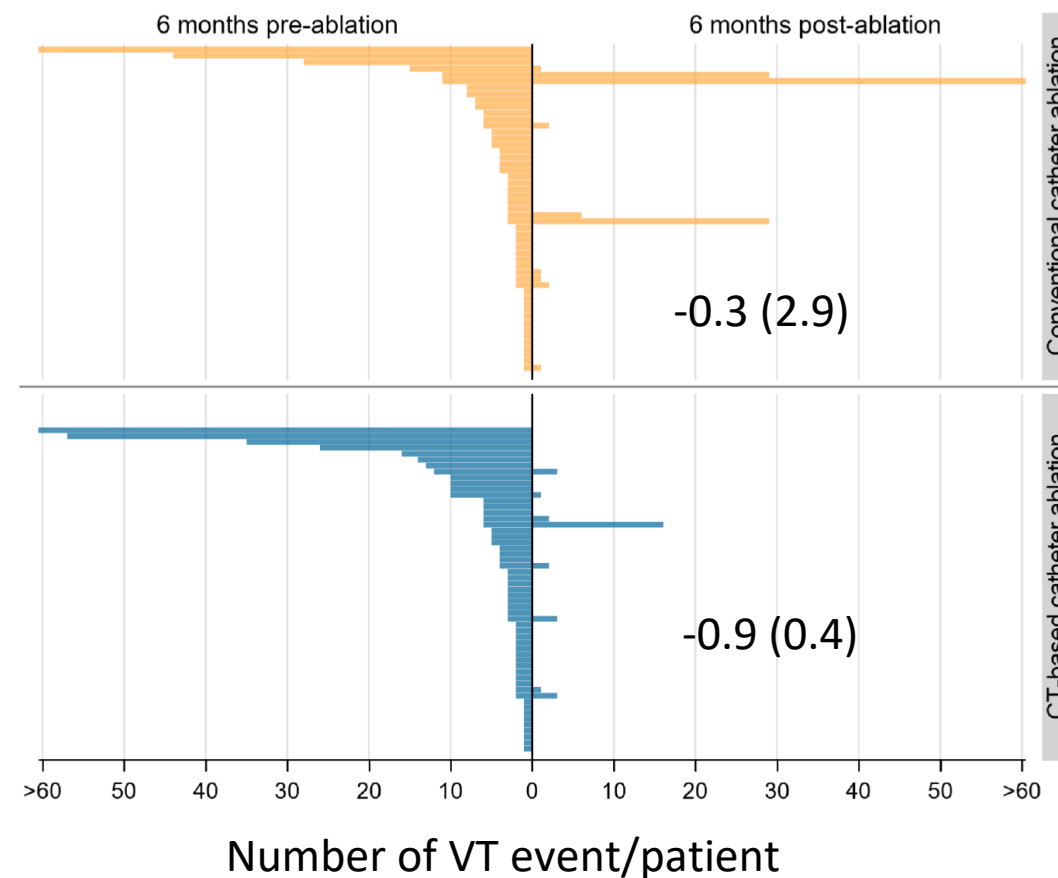
	Total (n=113)	Conventional VT ablation (n=56)	CT guided VT ablation (n=57)	Adjusted percentage difference
Mean procedure duration in ITT in min (SD)	134.4 (52.0)	148.8 (50.6)	120.3 (49.8)	-19.1% [-31.7 ; -6.6] p=0.0027
Mean procedure duration per protocole in min (SD)	129.3 (49.7)	148.8 (50.6)	107.1 (38.3)	-28.0% p<.0001

InEurHeart – secondary endpoints



	Total (n=113)	Conventional VT ablation (n=56)	CT guided VT ablation (n=57)	Stat
Absence of recurrence at one year (ITT)	80 (72.1%)	37 (67.3%)	43 (76.8%)	+ 9.5% NS
Absence of recurrence at one year (per-protocole) with CF catheter	74/101 (73.3%)	33/50 (66.0%)	41/51 (80.4%)	+ 14.4% NS

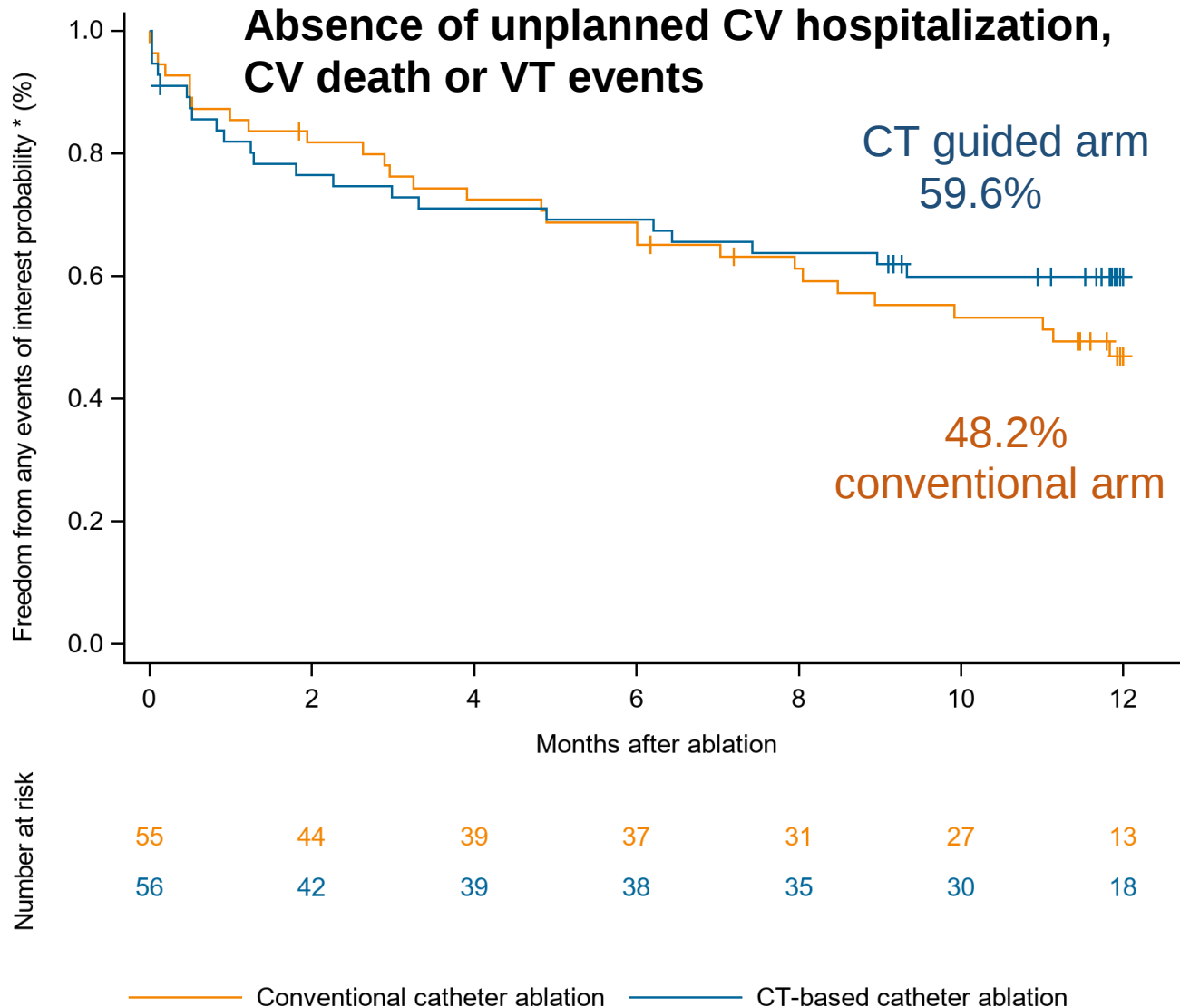
Reduction of VT burden



InEurHeart – secondary endpoints



Absence of unplanned CV hospitalization, CV death or VT events



Procedural cost

- in french public health system
- without GA
- without housing
- assuming a cost for image modelisation €1250

	Conventional	CT guided	Adjusted difference
Personal cost	€ 545,17	€ 392,39	€ 152,78
Material cost	€ 5 562,82	€ 5 069,90	€ 492,92
Total cost	€ 6107,99	€ 5462,29	€ 645,7 (-10.6%)

* Events of interest = Unplanned hospitalizations due to cardiac reasons, cardiovascular-related death and VT events

Digital twin of the infarct scar based on cardiac CT scan to guide VT ablation allows:

- **A reduction of procedure duration** by 19% (28% when the protocol was followed)
- **Without increased procedural risk**
- **With a one year VT free rate of 76.8% vs 67.3%** in the conventional group (NS)
- Procedural cost reduced by 10% in the CT-guided group.

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