Catheter Ablation of Ischemic Ventricular Tachycardia With Remote Magnetic Navigation: STOP-VT Multicenter Trial

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Design studie

- První prospektivní, nerandomizovaná (single arm), multicentrická klinická studie hodnotící úspěšnost RF ablace systémem dálkové magnetické navigace u ischemiků se setrvalou komorovou tachykardií.

- 53 pacientů ze 4 center v pilotním období 2009-2011
  - Homolka Hospital in Prague N=32
  - Hospital of the University of Pennsylvania N=10
  - University of Leipzig N=9
  - Methodist Hospital of Indianapolis N=2

Last 1y FUP completed 2012

Inclusion criteria

1. Setrvalá komorová tachykardie a průkaz ischemické jizvy

2. Věk 18 and 80 let

3. Není kontraindikace magnetického pole

4. Pacient podepsal inform. Souhlas schválený příslušnou etickou komisí

Exclusion Criteria

1. Mobilní trombus v levé komoře
2. Nepřítomnost současně mitrální a aortální mechanické chlopně
3. Není kontraindilace antikoagulace
4. Life expectancy nad 1 rok
5. Inkompatibilita CIED s magnetickým polem STX

Variable	Median or %, (IQR)	Frequency (n)
Age, y	67 (63-75)	53
Male, %	92.5%	49
History of:		
CABG, %	47.1%	25
PTCA, %	50.9%	27
CVA, %	17.0%	9
TIA, %	5.7%	3
Bleeding (other than CVA), %	3.8%	2
Respiratory disease, %	20.8%	11
Diabetes mellitus, %	30.2%	16
Kidney disease, %	22.6%	12
LV ejection fraction		
LVEF total %, (IQR)	31.5 (25-40)	53
LVEF <35 %	69.8%	37
LVEF 35-45%	26.4%	14
LVEF >45%	3.8%	2
Antiarrhythmic drugs		
Amiodarone	60.4%	32
Lidocaine	7.5%	4
Mexiletine	1.9%	1
Sotalol	0	0
Betablockers	87%	46

Table 2. Substrate Mapping

	Median or %	frequency (N)
Map Points		
Number of mapping points	152 (117-260)	
Chamber Map Volume		
LVV (mL, N=52)	260 (215 - 318)	
RVV (mL, N=3)	208 (80 – 235)	
Scar Location, coronary distribution (%)		
RCA	32.1%	17
RCA + LCX	26.4%	14
LAD	20.8%	11
LCX	17.0%	9
LAD + RCA	1.9%	1
not specified	1.9%	1
Pathological Potentials (%)		
Fractionated	83%	44
Late	81%	43
Double	55%	29

Table 3. Procedure Parameters

Variable	Median or %, (IQR)		frequency (N)
Number of VT morphologies per subject (%)			
1	45.3%		24
2	18.9%		10
3	20.8%		11
4	9.4%		5
5	3.8%		2
8	1.9%		1
All VT Cycle Length, sec	360 (307 – 410)	116	
Unstable VT Cycle Length, sec	298 (280 – 326)	53	
Unstable VT proportion, pts	58%		30
Unstable VT proportion, N of VTs	47%		53
Activated clotting times (ACT)			
Median after initial titration(sec)	323 (285 - 427)		

Active clotting times (ACT)

Median after initial titration(sec)	323 (285 - 427)

Approach Used

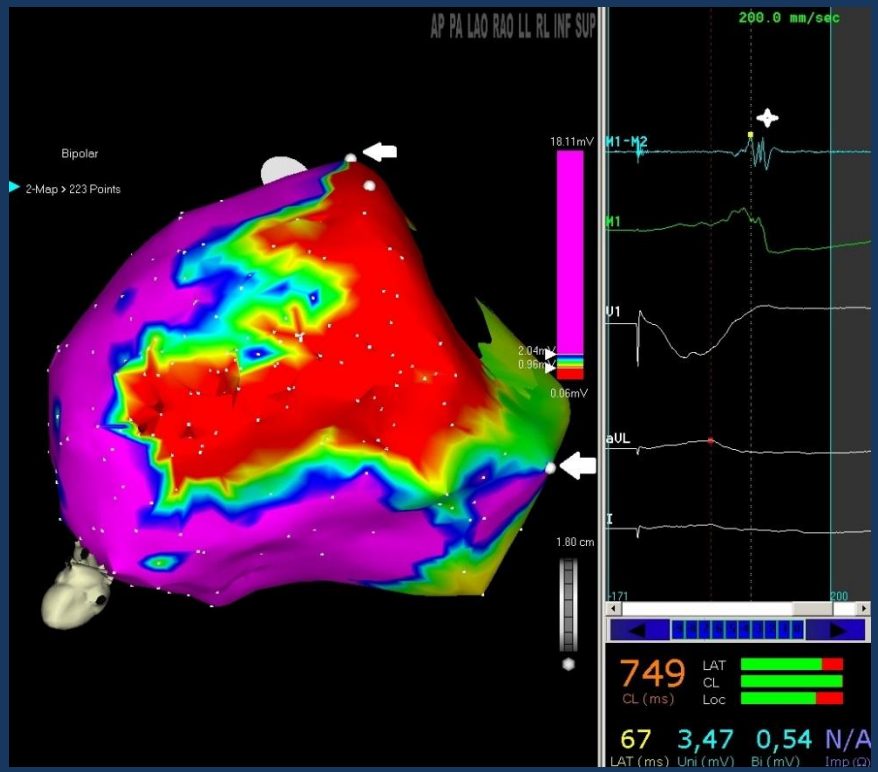
Retrograde, % (N=5)	9.4%
Transseptal, % (N=48)	90.6%

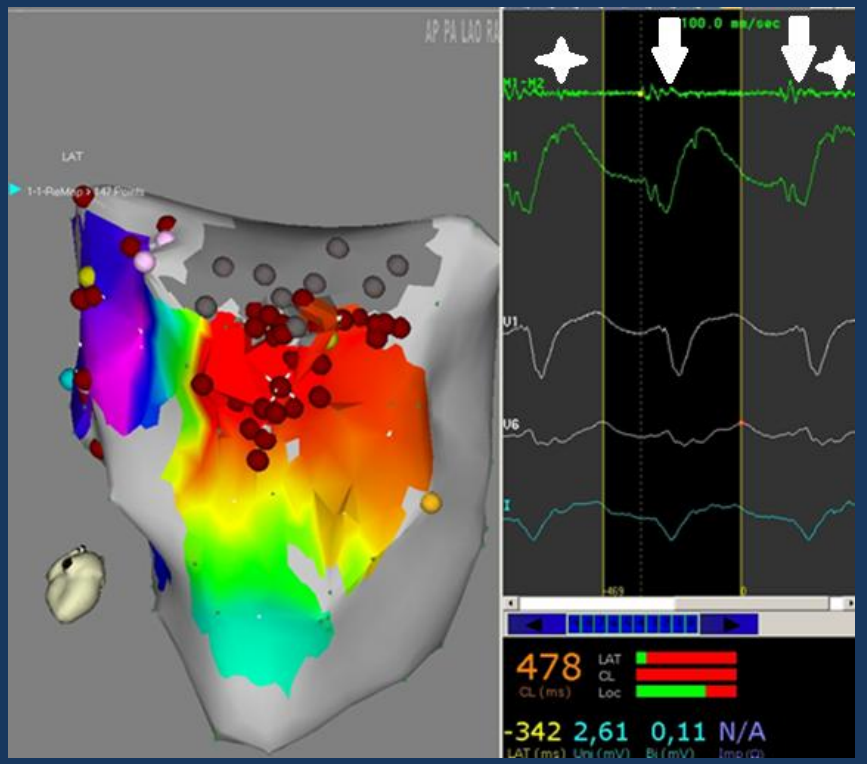
Ablation Summary

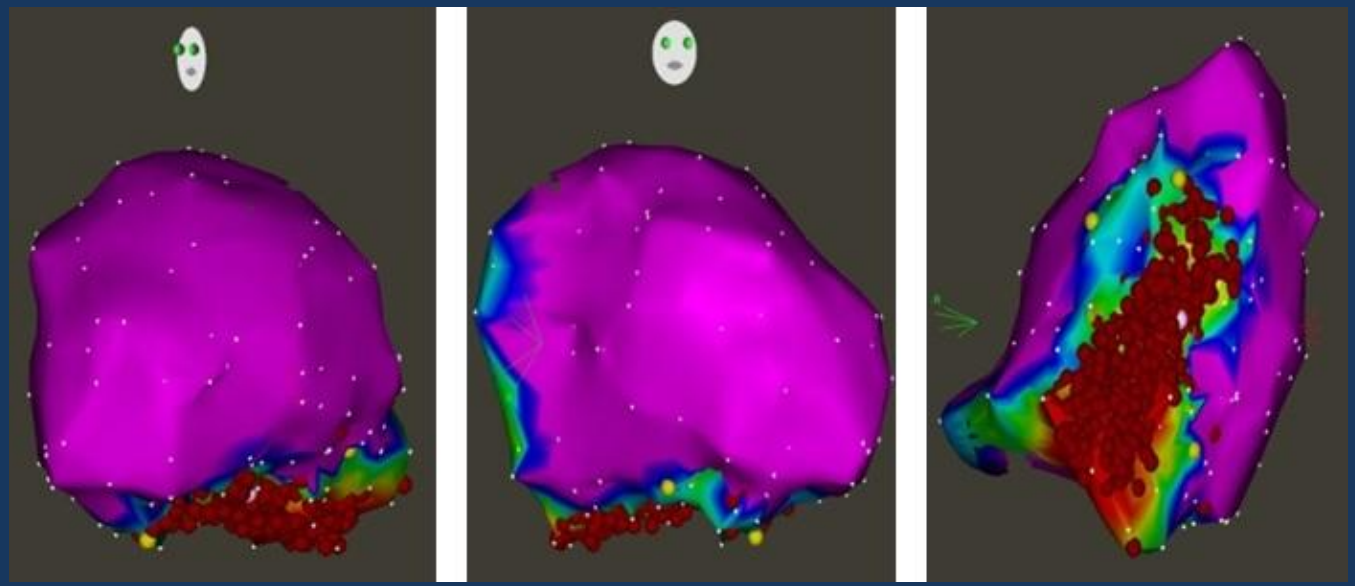
Maximum Temperature (°C, N=1313)	38.8 (36 - 41)
Impedance (Ohms, N=1313)	111.0 (94 - 127)
Maximum Power (watts, N=1313)	42.3 (39 - 50)
Ablation Duration (sec, N=52)	60 (59 - 90)
Total Ablation Time (min, N=52)	37.8 (17.8 – 48.0)

Procedure and Flouroscopy Times

Elapsed time of Procedure (min, N=52)	220 (176 – 292)
Flouro Exposure Time before Mapping (min)	6.7 (4.2 – 9.6)
Flouro Exposure Time - Mapping (min)	0.48 (0.2 – 2.5)
Flouro Exposure Time - Ablation (min)	0.46 (0.1 – 2.8)
Total Flouro Exposure Time (min)	8.65 (5.3 – 16.5)


AP PA LAO RAO LL RL INF SUP
200.0 mm/sec
Bipolar
2-Map > 223 Points
18.11mV
2.04mV
0.96mV
0.06mV
1.80 cm
M1-M2
M1
U1
aUL
I
749
CL (ms)
LAT
CL
Loc
67
LAT (ms)
3,47
Uni (mV)
0,54
Bi (mV)
N/A
Imp (Ω)


AP PA LAO RA
100.0 mm/sec
LAT
M1-M2
M1
U1
V6
I
478
CL (ms)
LAT
CL
Loc
-342
LAT (ms)
2,61
Uni (mV)
0,11
Bi (mV)
N/A
Imp (Ω)




I
II
III
aVF
aVR
aVL
V1
V2
V3
V4
V5
V6
100 ms
C ABL d
352 msec
170 BPM
329 msec
182 BPM
C ABL p
C CS 1,2
C CS 3,4
C CS 5,6
C CS 7,8
C CS 9,10
RVa d
200 mmHg
CardioLab v6.5.6
GE Healthcare

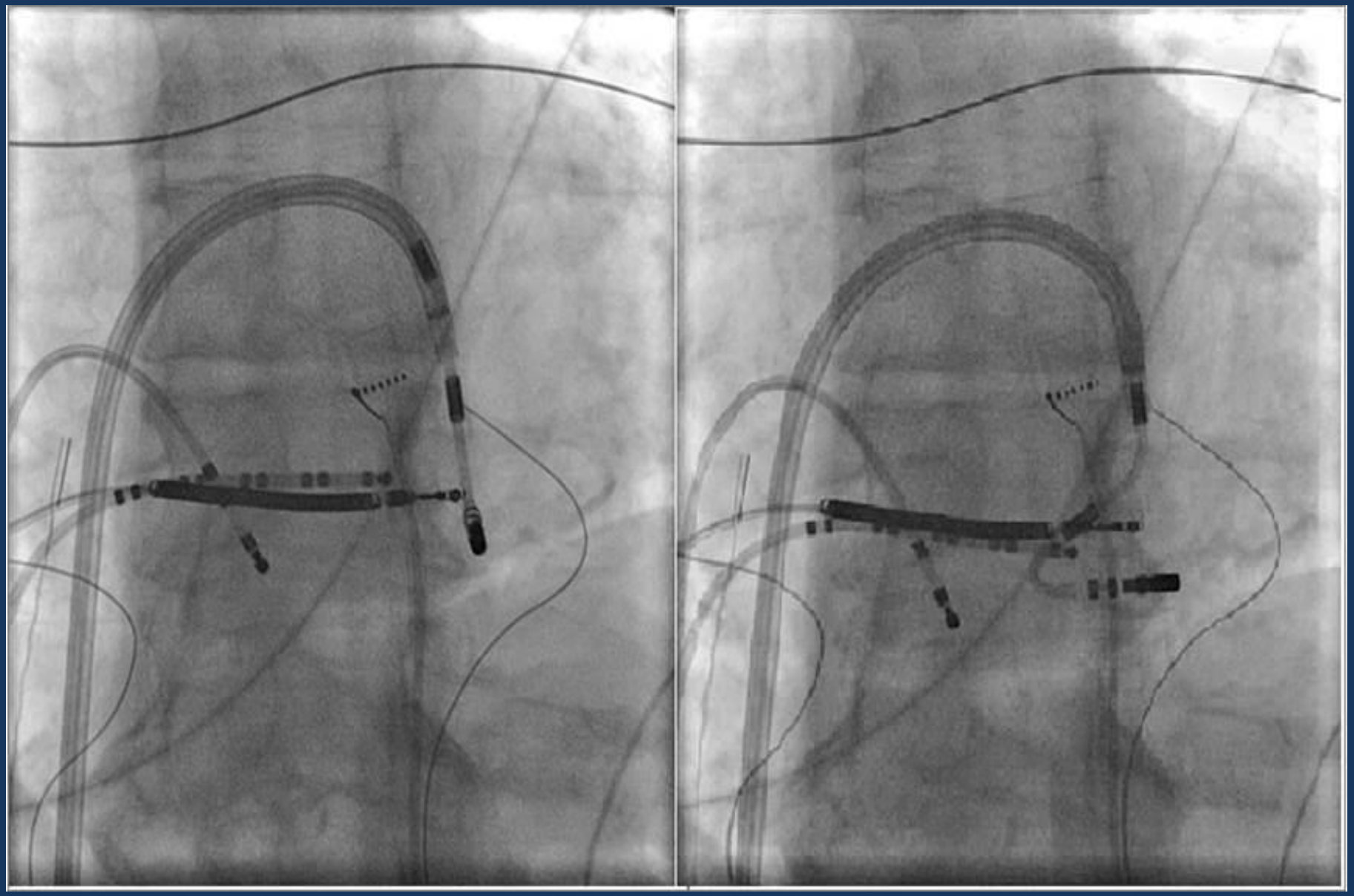
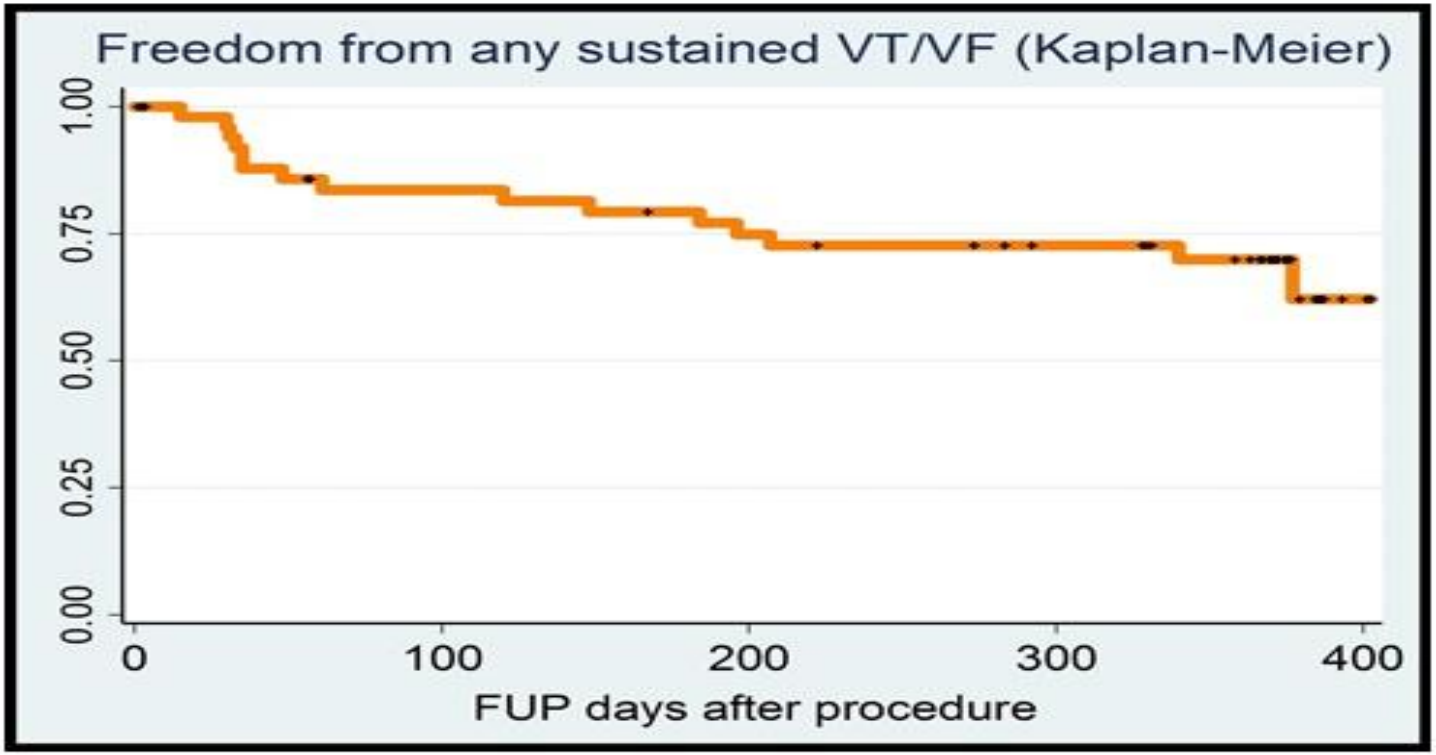


Table 2. Acute Ablation Success

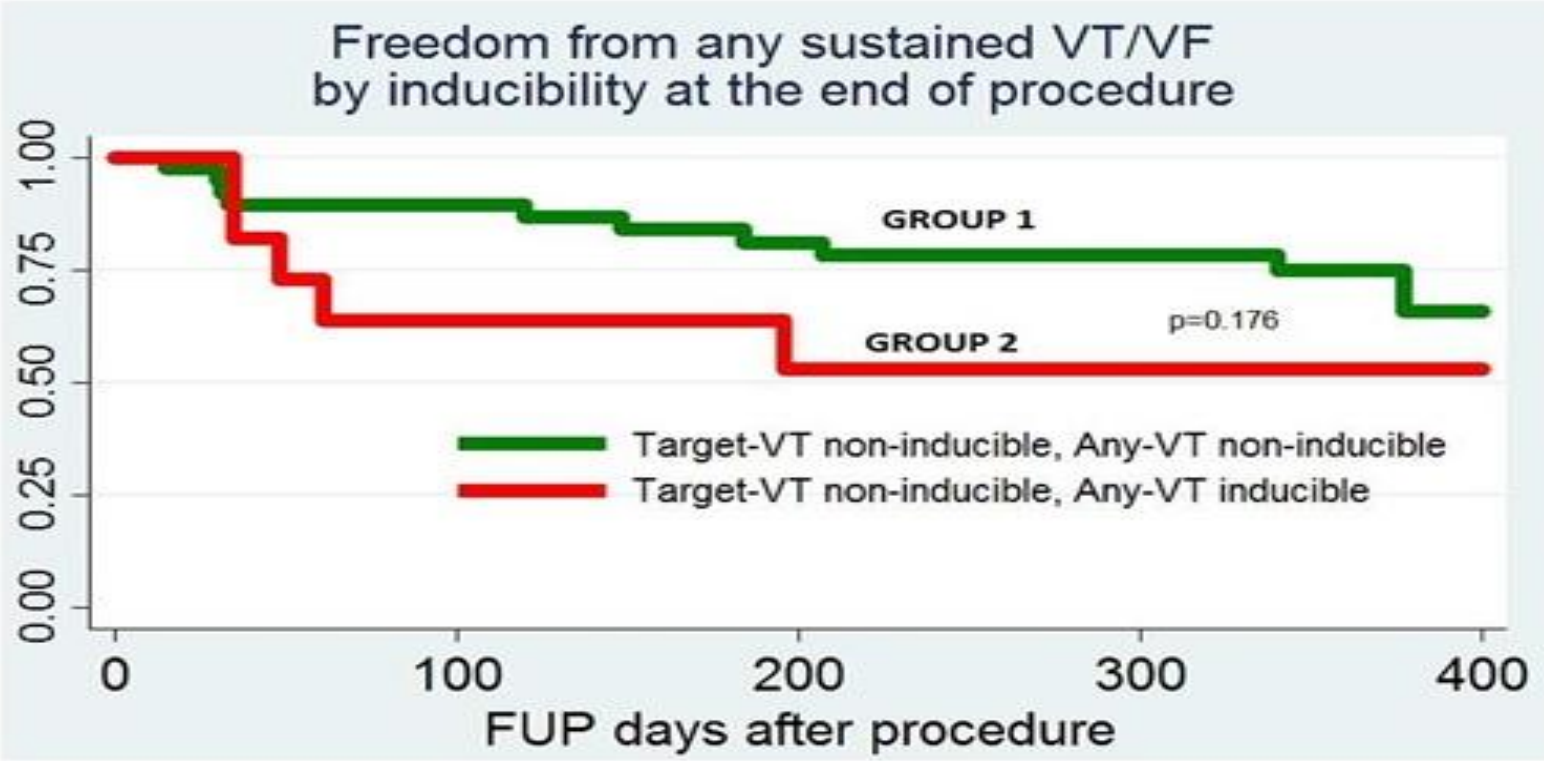
Acute Success	N	%
Target VT non-inducible	49/52	94.2%
Any VT non-inducible	38/52	73.6%
Procedure failure	3/52	5.8%



To be included in a long-term success table the patient must be an acute success

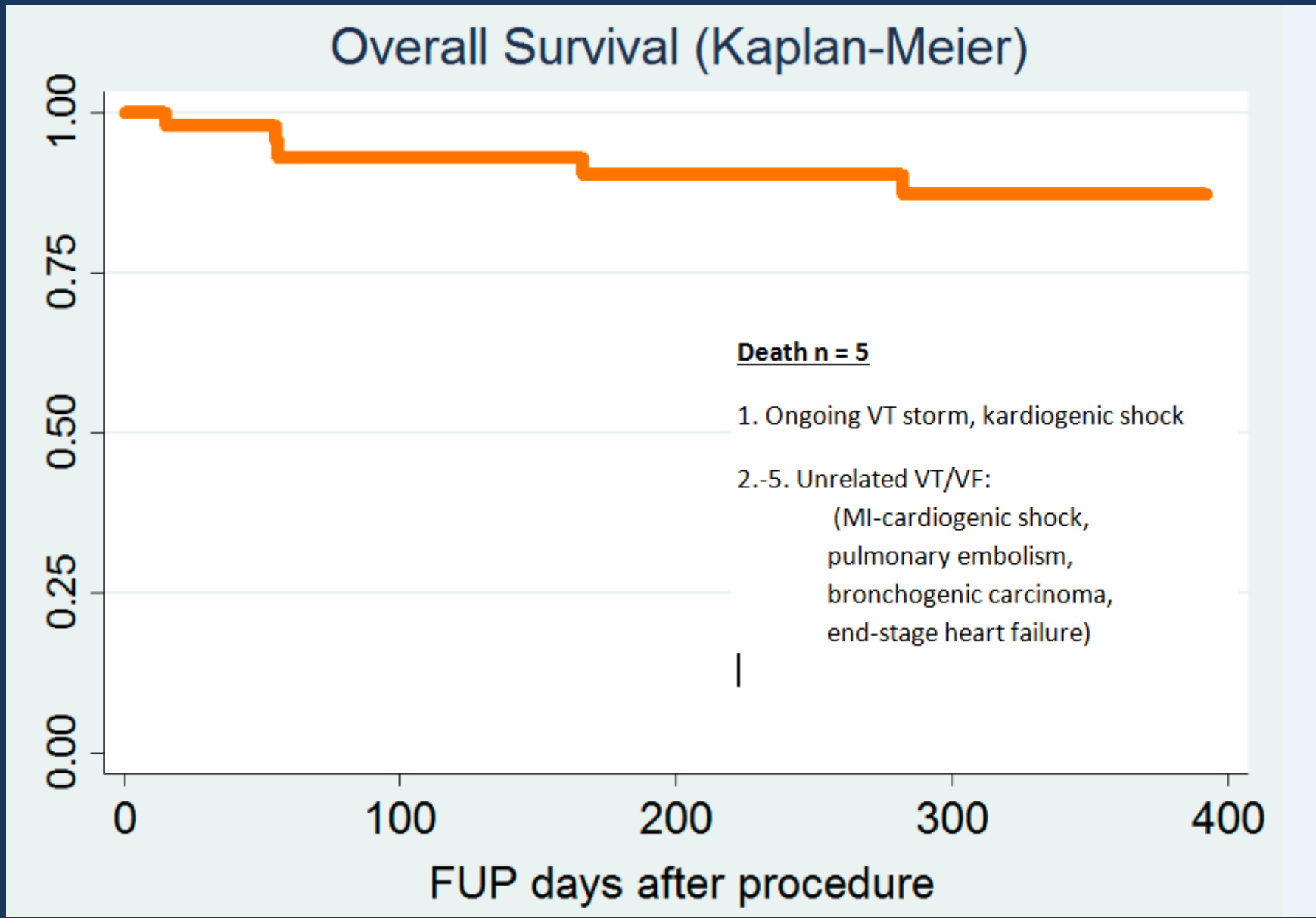
ICD Follow-up (months)	At-Risk (n)	Recurrent VTs (n)	Censored (n)	Cumulative freedom from any sustained VT (%)
1 month	49	8	2	84%
6 months	39	5	2	73%
12 months	32	2	30	62%

12 months off anti-arrhythmic drugs: 19 of 30 (63%) event-free patients



Follow-up (months)	At-Risk (n)	Recurrent VTs (n)	Censored (n)	Cumulative freedom from any sustained VT/VF (%)
Ablation	38/14	0/0	0/0	100/100%
1 month	38/11	4/4	2/0	89/64%
6 months	32/7	4/1	1/1	78/53%
12 months	27/5	2/0	25/5	65/53%

Numbers depicted as group 1/ group 2


Overall Survival (Kaplan-Meier)
1.00
0.75
0.50
0.25
0.00
0
100
200
300
400
FUP days after procedure
Death n = 5
1. Ongoing VT storm, kardiogenic shock
2.-5. Unrelated VT/VF:
(MI-cardiogenic shock,
pulmonary embolism,
bronchogenic carcinoma,
end-stage heart failure)

Závěr

- První prospektivní multicentrická pilotní studie ověřila účinnost dálkové magnetické navigace v katetrizační ablaci setrvalé monomorfní komorové tachykardie.

- Tohoto cíle bylo dosaženo bez komplikací a s minimální rentgenovým časem (< 1 min) během mapování a ablace.

- Na slibné výsledky této pilotní studie navazuje r.2016 nábor pacientů do randomizované studie vůči manuálnímu EA katetru (MAGNETiC-VT- Study)

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