PRAGUE RHYTHM

HPSD

High Power Short Duration Ablation

Jose L. Merino, FEHRA

Hospital Universitario La Paz

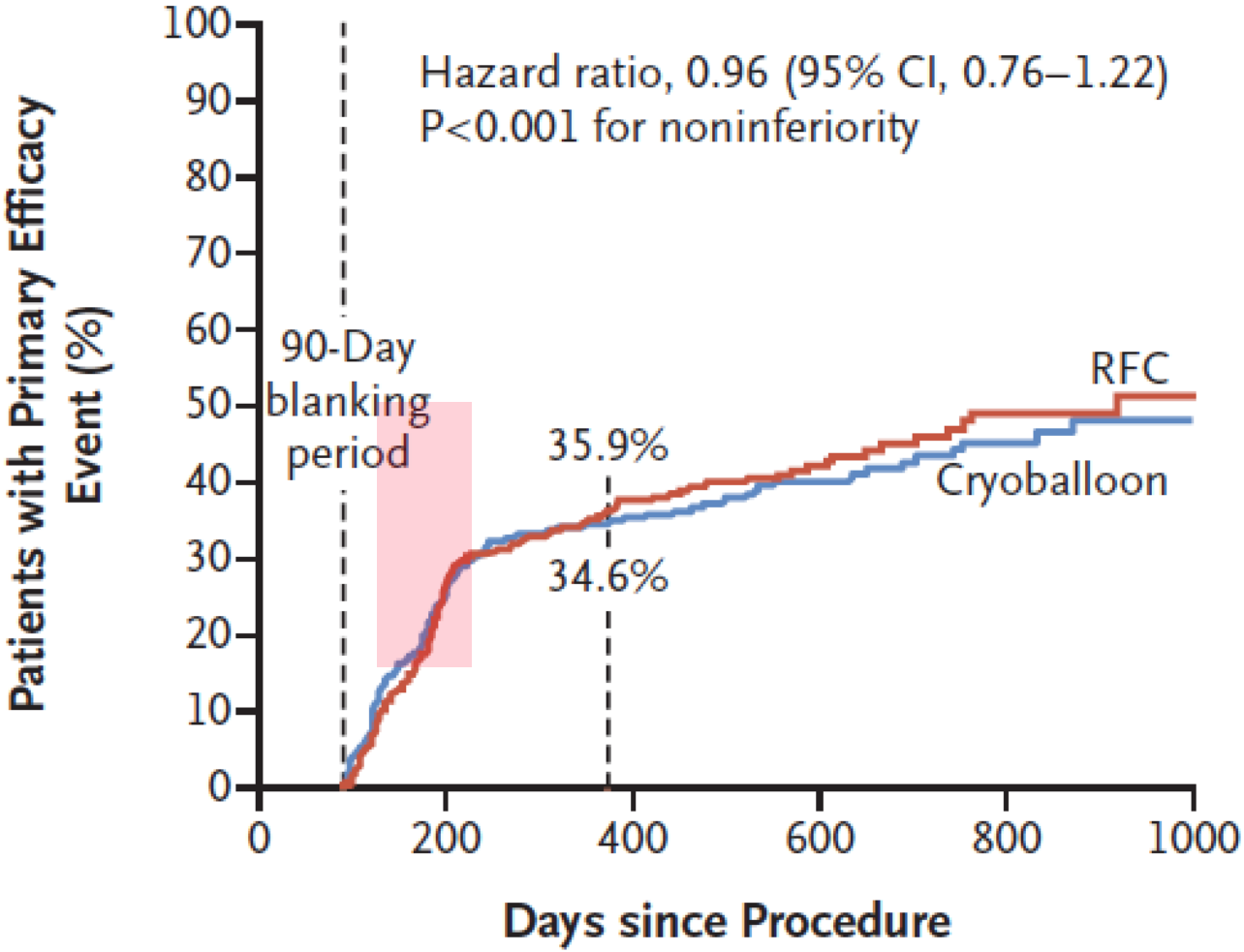
SaludMadrid

Conflict of Interest

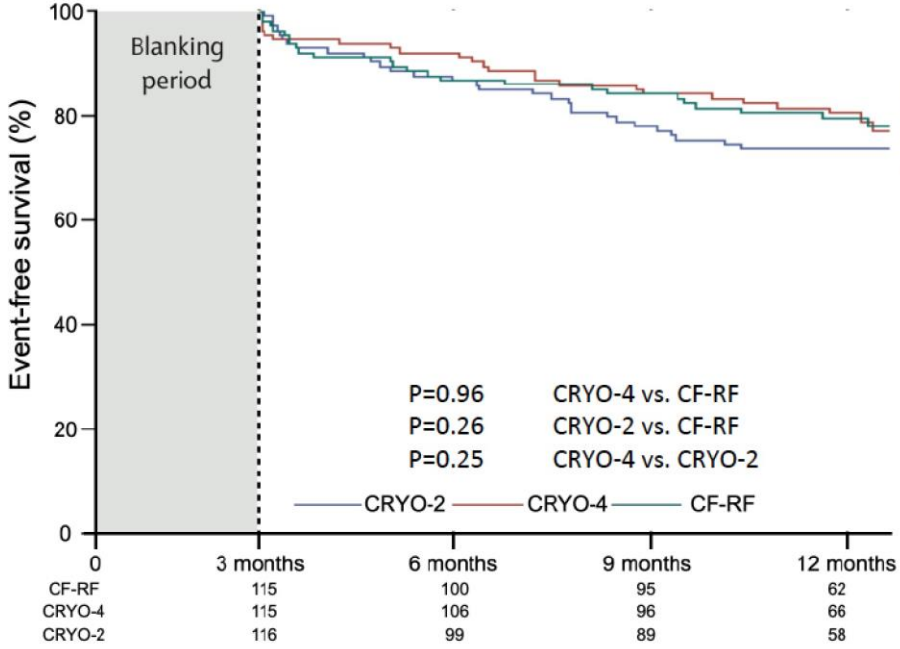
- Advisory board: Sanofi
- Research grants: Abbott, Boston Scientific, Medtronic
- Educational fees/contracts: Abbott, Microport

PRAGUE RHYTHM

Efficacy


Hazard ratio, 0.96 (95% CI, 0.76–1.22)
P<0.001 for noninferiority
Patients with Primary Efficacy Event (%)
100
90
80
70
60
50
40
30
20
10
0
90-Day blanking period
35.9%
34.6%
RFC
Cryoballoon
0
200
400
600
800
1000
Days since Procedure

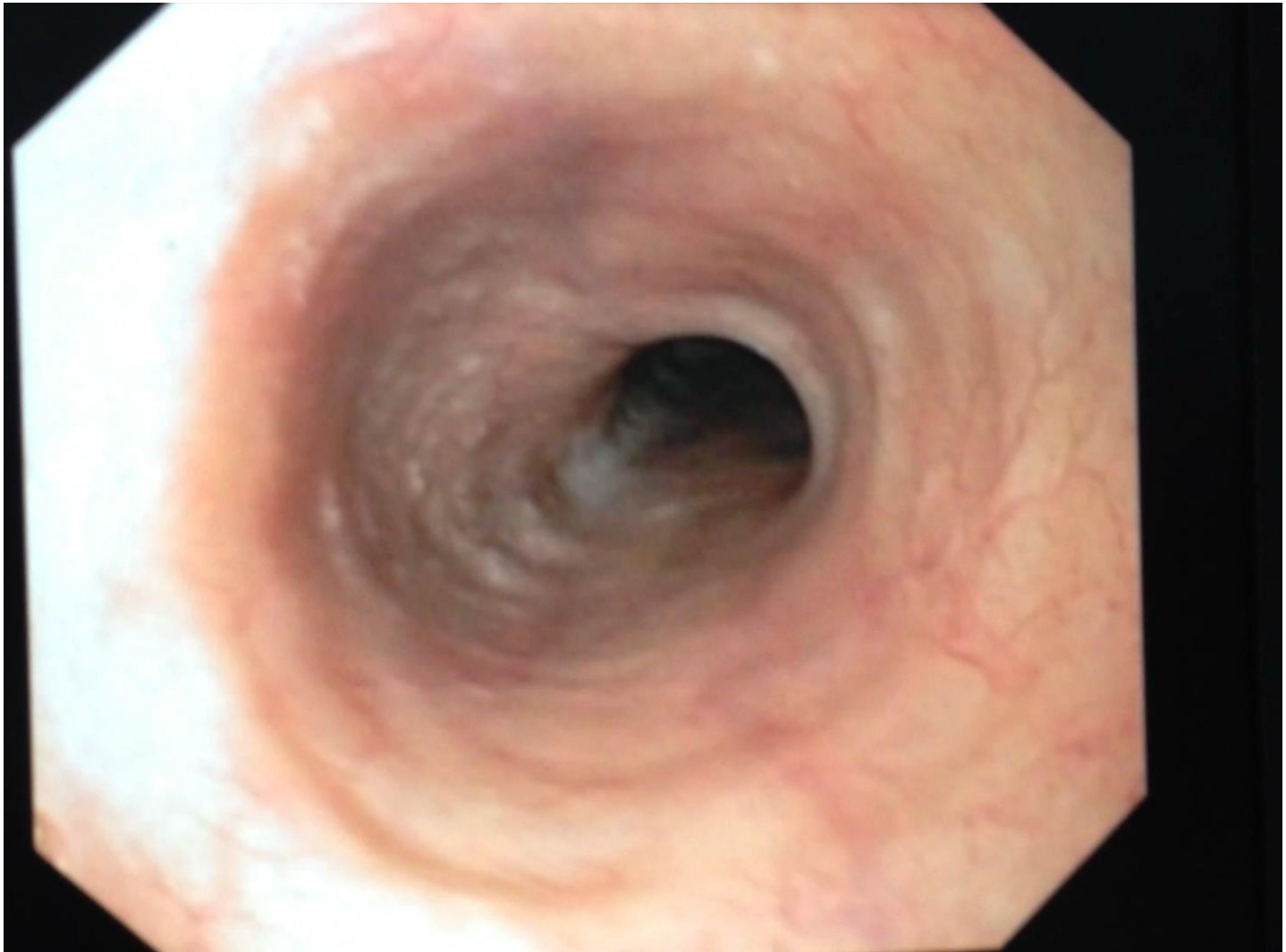
Secondary Outcome – freedom from **symptomatic** tachyarrhythmia (AF/AFL/AT) after a single ablation procedure



CIRCA DOSE

PRAGUE RHYTHM

Safety



PRAGUE RHYTHM

IMAGE FOCUS

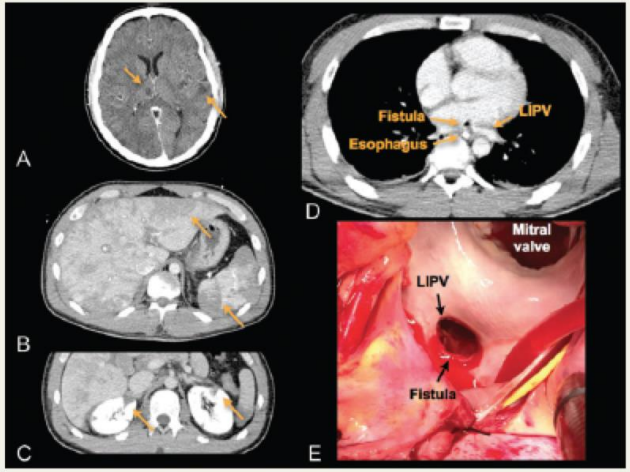
doi:10.1093/ehjci/jet143
Online publish-ahead-of-print 7 August 2013

Atrioesophageal fistula secondary to pulmonary vein cryo-ablation

David Viladés Medel[1]*, Julio Marti-Almor[2], Jose Montiel Serrano[3], Alessandro Sionis[4], and Rubén Leta Petracca[1]

[1]Cardiac Imaging Unit, Cardiology Department, Hospital Santa Creu i Sant Pau, Barcelona, Spain; [2]Electrophysiology Unit, Hospital del Mar, Barcelona, Spain; [3]Cardiac Surgery Department, Hospital Santa Creu i Sant Pau, Barcelona, Spain; and [4]Cardiac Intensive Care Unit, Hospital Santa Creu i Sant Pau, Barcelona, Spain

*Corresponding author. Tel: 0034935565945; Fax: 0034935565603, Email: dvilades@santpau.cat



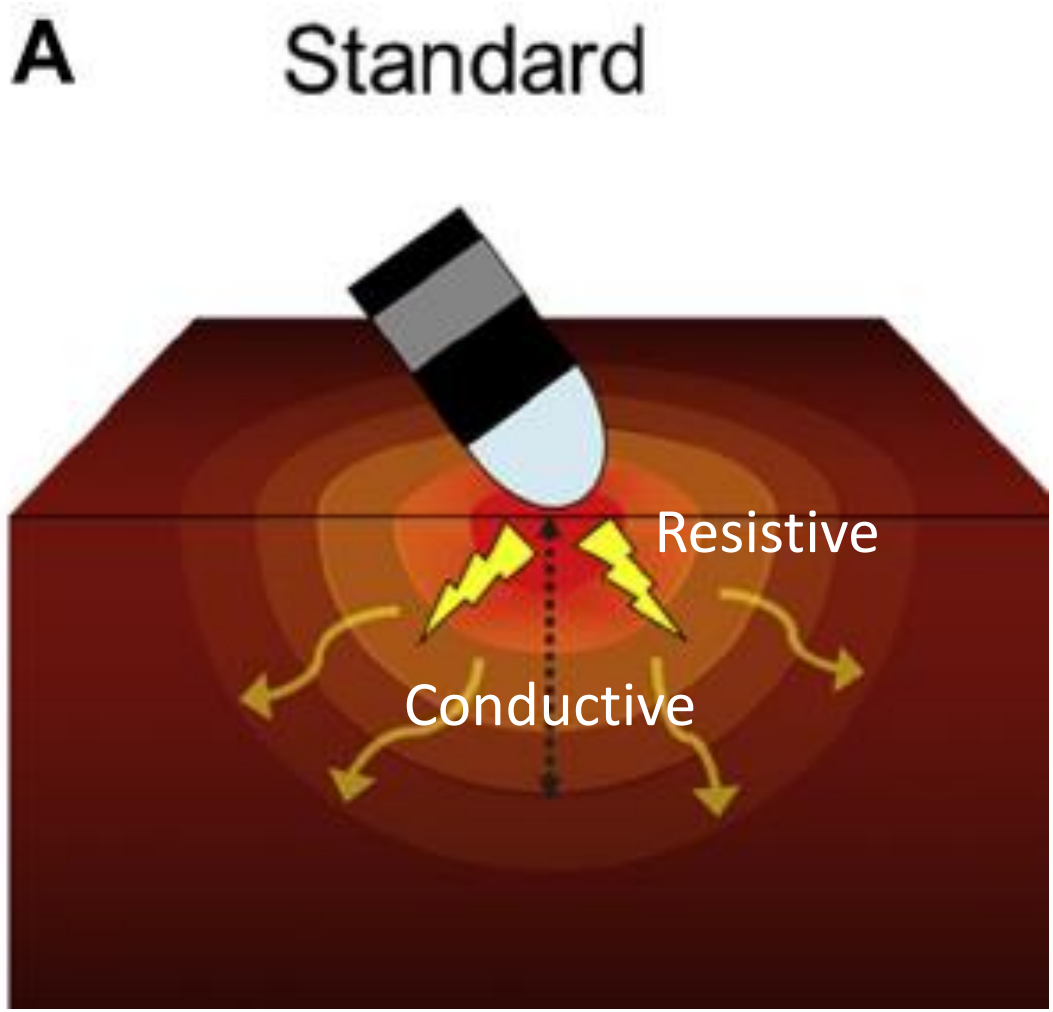
We report the case of a 31-year-old man with paroxismal atrial fibrillation treated with pulmonary vein isolation (PVI) with cryo-balloon. Early after discharge he presented a transient mild haemoptysis and fever. Four weeks later he was re-admitted for recurring fever, headache, and absence seizures. Brain-CT scan showed multiple bilateral hemispheric emboli (*Panel A*). A transoesophageal echocardiography did not show valvular vegetations or intracardiac thrombosis. He then required intubation and mechanical ventilation due to rapidly progressive loss of consciousness. A 12-lead electrocardiogram showed persistent ST-segment elevation in inferior leads and subsequent coronary angiogram showed the absence of coronary artery disease, but a markedly slow flow in the right coronary artery. Laboratory tests showed progressive kidney and liver failure as well as intravascular disseminated coagulopathy. A screening chest-abdominal-pelvic CT revealed multiple liver, spleen, and kidney emboli (*Panels B* and *C*, arrows). A careful exam of the thoracic images showed a very low density area in the left atrium near the ostium of the left inferior pulmonary vein (LIPV), probably due to an atrioesophageal fistula (*Panel D*, arrow).

Cardiac surgery confirmed a laceration in the ostium of the LIPV (*Panel E*) which was repaired with a pericardial patch. Despite of this, the patient's clinical condition worsened presenting incontrollable intracraneal bleeding and refractory septic shock leading to death 24 h after surgery.

To our knowledge, this is the second reported case of atrioesophageal fistula secondary to PVI with cryo-balloon. Interestingly, in both cases the involved vessel was the LIPV.

D.V.M. is supported by a research grant from Toshiba Medical Systems, Spain.

RF basis



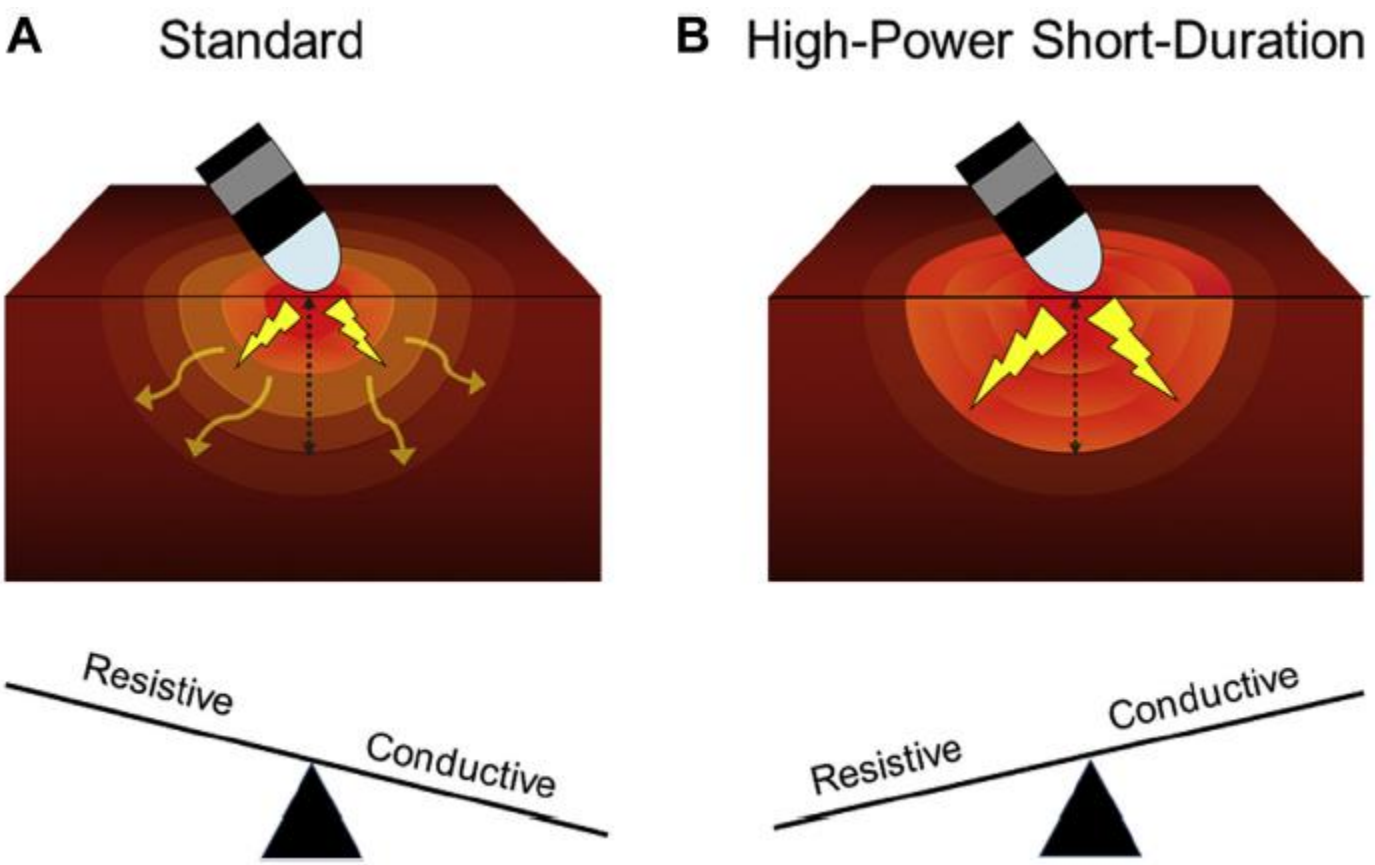
Leshem et al. JACC EP. 2018

What is “conventional” RF application?

Experience with contact force (CF) sensing catheters	n	W
Casella et al. 2014	20	35
Kimura et al. 2014	19	25-30
Pedrote et al. 2016	25	25-35
Nakamura et al. 2015	60	30-40
Ullah et al. 2016	59	30
Reddy et al. 2015	152	¿?
Sigmund et al. 2015	99	25-35
Jarman et al. 2015	200	25-35
Deubner et al. 2016	96	20-30
Martinek et al. 2012	25	25-35
Makimoto et al. 2015	35	30-40
Ullah et al. 2014	50	¿?
Wutzler et al. 2014	31	35
Wakili et al. 2014	32	30
Andrade et al. 2014	25	25-35
Fichtner et al. 2015	30	25-30
Rosso et al. 2016	50	25-30
Marijon et al. 2014	30	25-30
Itoh et al. 2016	50	20-30
Wolf et al. 2016	24	30-40
Lee et al. 2016	510	30
Sciara et al. 2014	21	20-30
Taghi et al. 2018	130	25-35
Phlips et al. 2018	50	35
“Conventional” RF power: 25 – 30 W		

25-30W

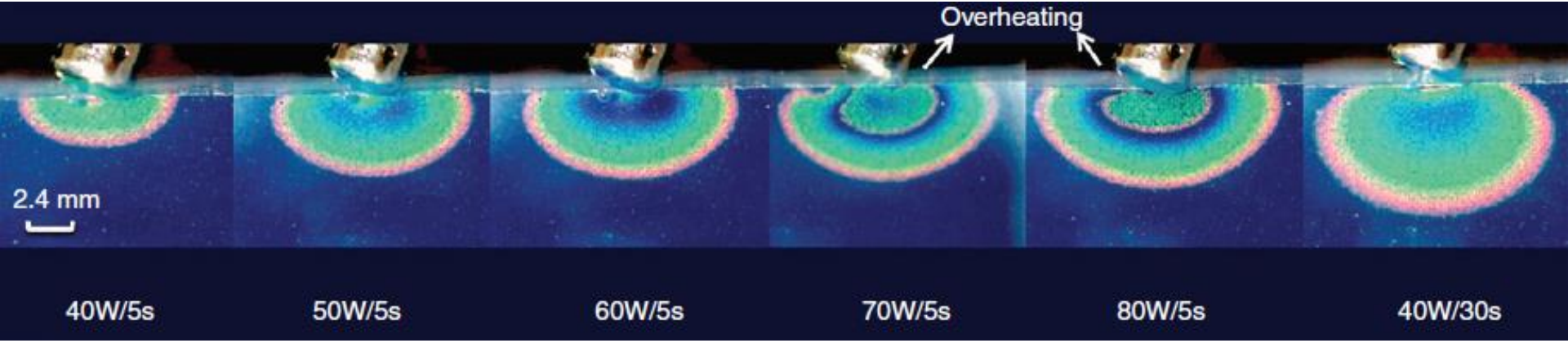
PRAGUE RHYTHM



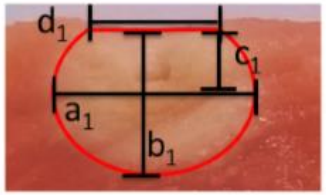
Leshem et al. JACC EP. 2018

Five seconds of 50–60 W radio frequency atrial ablations were transmural and safe: an *in vitro* mechanistic assessment and force-controlled *in vivo* validation

Conventional



Bashkaran et al. Europace. 2017

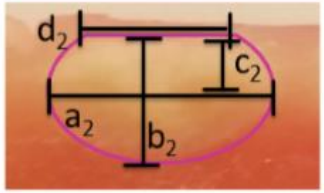


Standard 30W, 30s, 15-20g

a_1 = 8.9±0.6mm c_1 = 2.2±0.5mm

b_1 = 5.7±0.6mm d_1 = 7.5±0.6mm

Volume$_1$ = 271±46mm^3

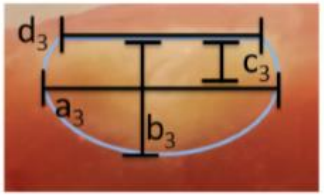


HPSD 50W, 13s, 15-20g

a_2 = 10.2±0.5mm c_2 = 1.0±0.4mm

b_2 = 4.7±0.6mm d_2 = 8.9±0.4mm

Volume$_2$ = 274±34mm^3

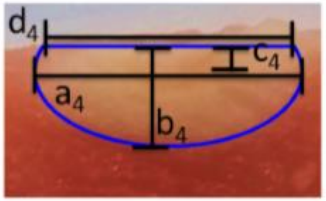


HPSD 60W, 10s, 15-20g

a_3 = 10.4±0.6mm c_3 = 0.6±0.3mm

b_3 = 4.3±0.5mm d_3 = 9.4±0.5mm

Volume$_3$ = 259±36mm^3

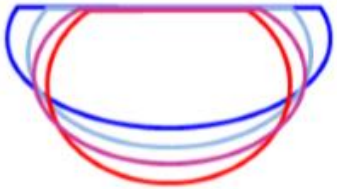


HPSD 70W, 7s, 15-20g

a_4 = 11.2±0.5mm c_4 = 0.6±0.2mm

b_4 = 3.9±0.5mm d_4 = 10.3±0.6mm

Volume$_4$ = 272±40mm^3



Overlay view of schematic lesion geometries

(30W 30s red, 50W 13s purple, 60W 10s light blue, 70W 7s blue)

PRAGUE RHYTHM

Bourier et al. Journal of Cardiovascular Electrophysiology 2018

FISTESO study

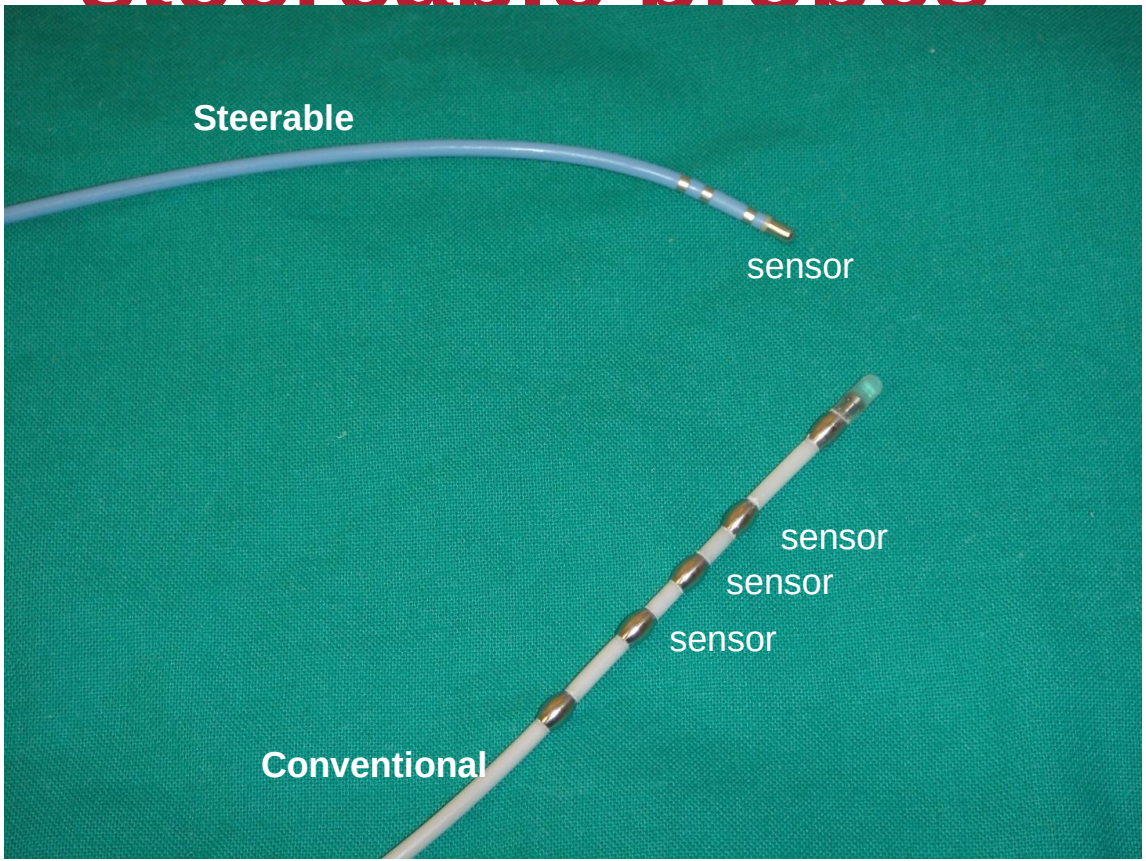
PRAGUE RHYTHM

Methods

- 32 p with AF:
  - 21 male
  - 68 yo
  - 64% paroyxsmal AF
- Point-by-point RF
- Luminal Esophageal Thermometer (LET)

PRAGUE RHYTHM

Conventional and steereable probes



PRAGUE RHYTHM

Ablation

- RF1: 30 W x 30 sec (tº <48ºC, 17 ml/min)
- If LET>40 ºC (RF1):

↓ 30 sec

- RF2: 30 W x 30 sec (same point)

↓ following LET<37ºC

- RF3: 20 W x 60 sec (same point)

PRAGUE RHYTHM

Results

	30W x 30 sec	20W x 60 sec	
	RF1	RF3	P
LET (ºC)	41.8±3.1	42.6±3.3	<0.0001

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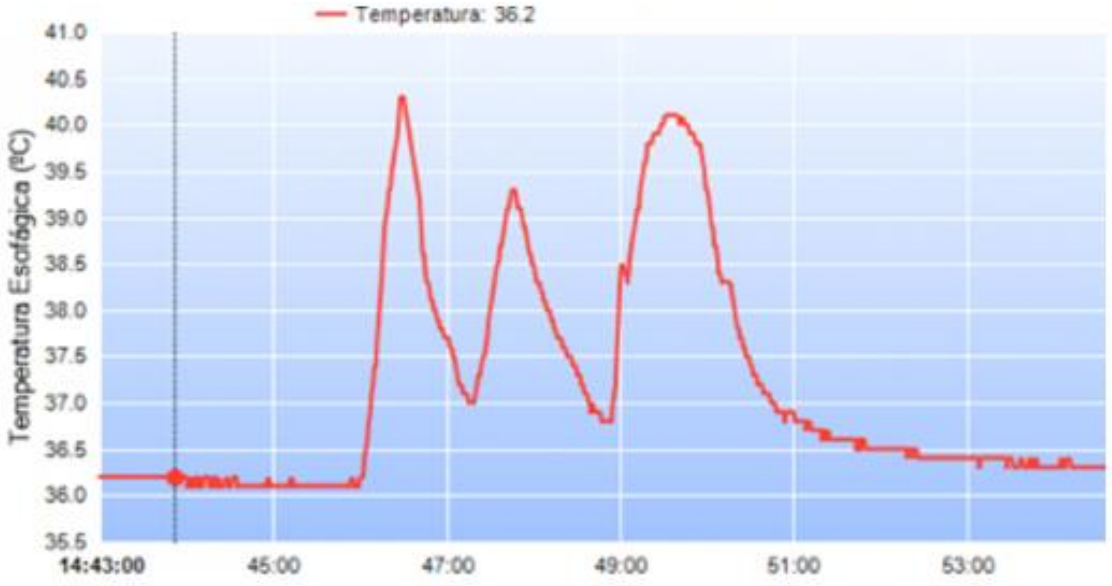
LET curve



PRAGUE RHYTHM

POWER-FAST studies

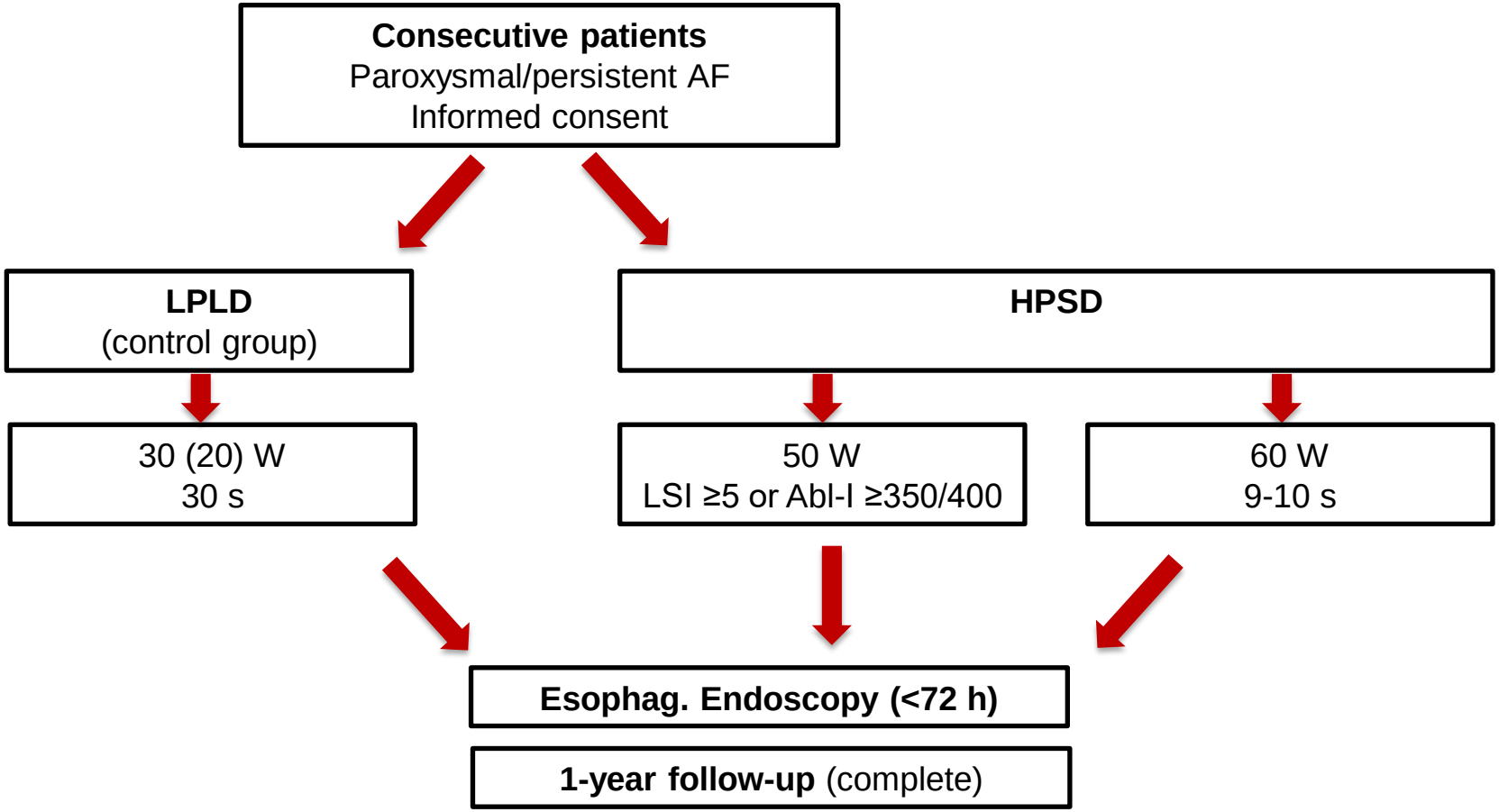
PRAGUE RHYTHM

Journal of Interventional Cardiac Electrophysiology
https://doi.org/10.1007/s10840-019-00645-5

Feasibility and safety of pulmonary vein isolation by high-power short-duration radiofrequency application: short-term results of the POWER-FAST PILOT study

Sergio Castrejón-Castrejón[1] · Marcel Martínez Cossiani[1] · Marta Ortega Molina[1] · Carlos Escobar[1] · Consuelo Froilán Torres[2] · Nerea Gonzalo Bada[2] · Marta Díaz de la Torre[2] · José Manuel Suárez Parga[2] · José Luis López Sendón[1] · José Luis Merino[1]

Received: 9 June 2019 / Accepted: 9 October 2019


Consecutive patients
Paroxysmal/persistent AF
Informed consent
LPLD
(control group)
HPSD
30 (20) W
30 s
50 W
LSI ≥5 or Abl-I ≥350/400
60 W
9-10 s
Esophag. Endoscopy (<72 h)
1-year follow-up (complete)

Acute Efficacy

	LPLD	HPSD		p
	30 W	50 W	60 W	
Patients with PVI of all targeted PV	96%	100%	100%	0.59
PV first-pass isolation	39%	57%		0.01
		56%	58%	0.05

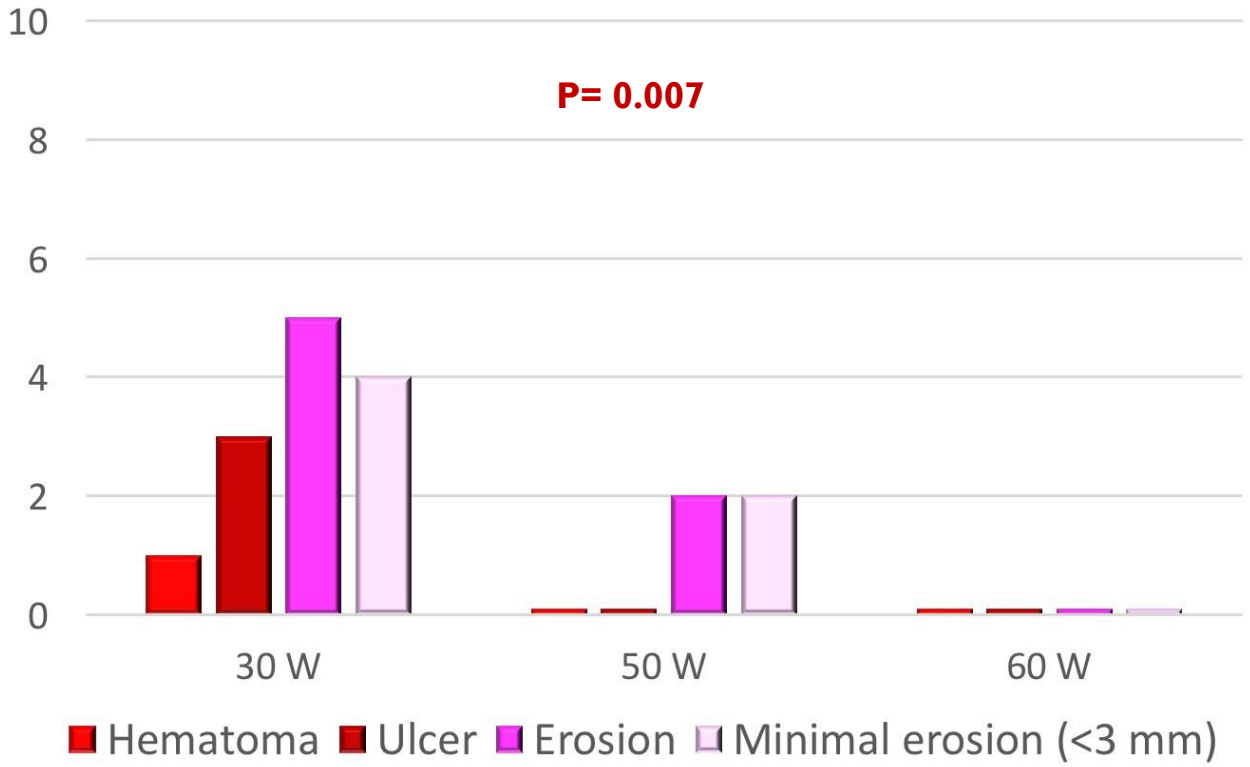
PRAGUE RHYTHM

Complications

	LPLD (47)	HPSD 50 W (18)	HPSD 60 W (30)
Peric. Effusion	3	0	0
Vascular	3	0	0
PV stenosis	1	0	0
TIA (48 h)	0	0	1

PRAGUE RHYTHM

Eosaphageal lessions



PRAGUE RHYTHM

ESC European Society of Cardiology

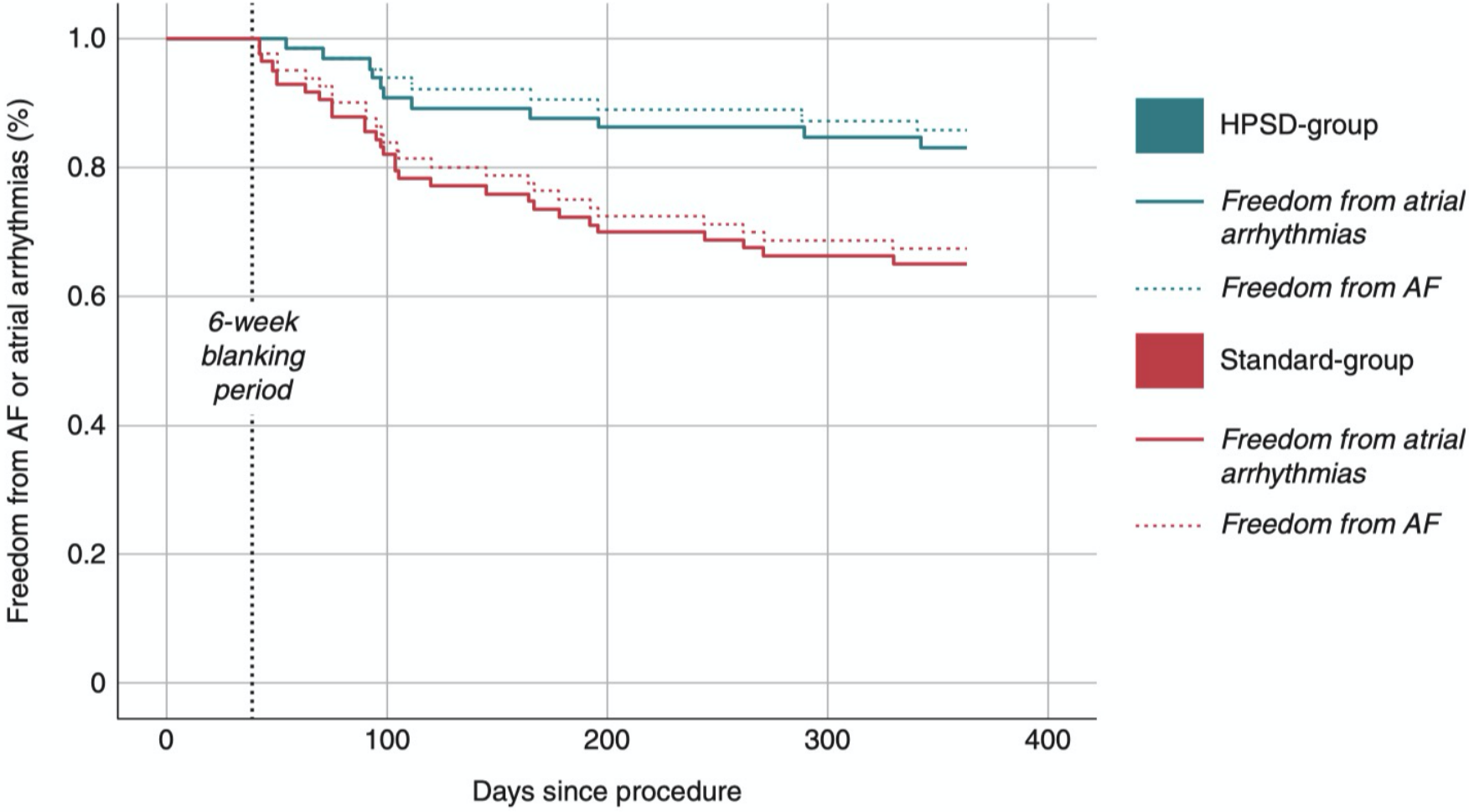
Europace (2019) **0**, 1–6
doi:10.1093/europace/euz342

CLINICAL RESEARCH

Safety and outcome of very high-power short-duration ablation using 70 W for pulmonary vein isolation in patients with paroxysmal atrial fibrillation

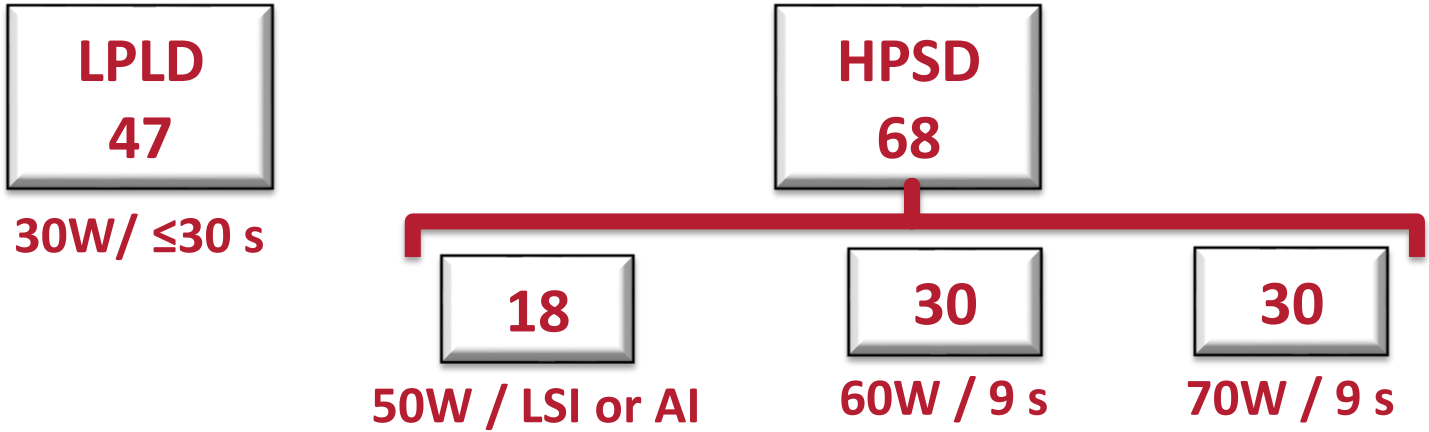
Marc Kottmaier*, Miruna Popa, Felix Bourier, Tilko Reents, Jairo Cifuentes, Verena Semmler, Martha Telishevska, Ulamnemekh Otgonbayar, Katharina Koch-Büttner, Carsten Lennerz, Marcin Bartkowiak, Marielouise Kornmayer, Elena Rousseva, Amir Brkic, Christian Grebmer, Christoph Kolb, Gabriele Hessling, and Isabel Deisenhofer

RHYTHM


1.0
0.8
0.6
0.4
0.2
0
Freedom from AF or atrial arrhythmias (%)
6-week blanking period
0
100
200
300
400
Days since procedure
HPSD-group
Freedom from atrial arrhythmias
Freedom from AF
Standard-group
Freedom from atrial arrhythmias
Freedom from AF

POWER-FAST II

- **125 consecutive AF pts**



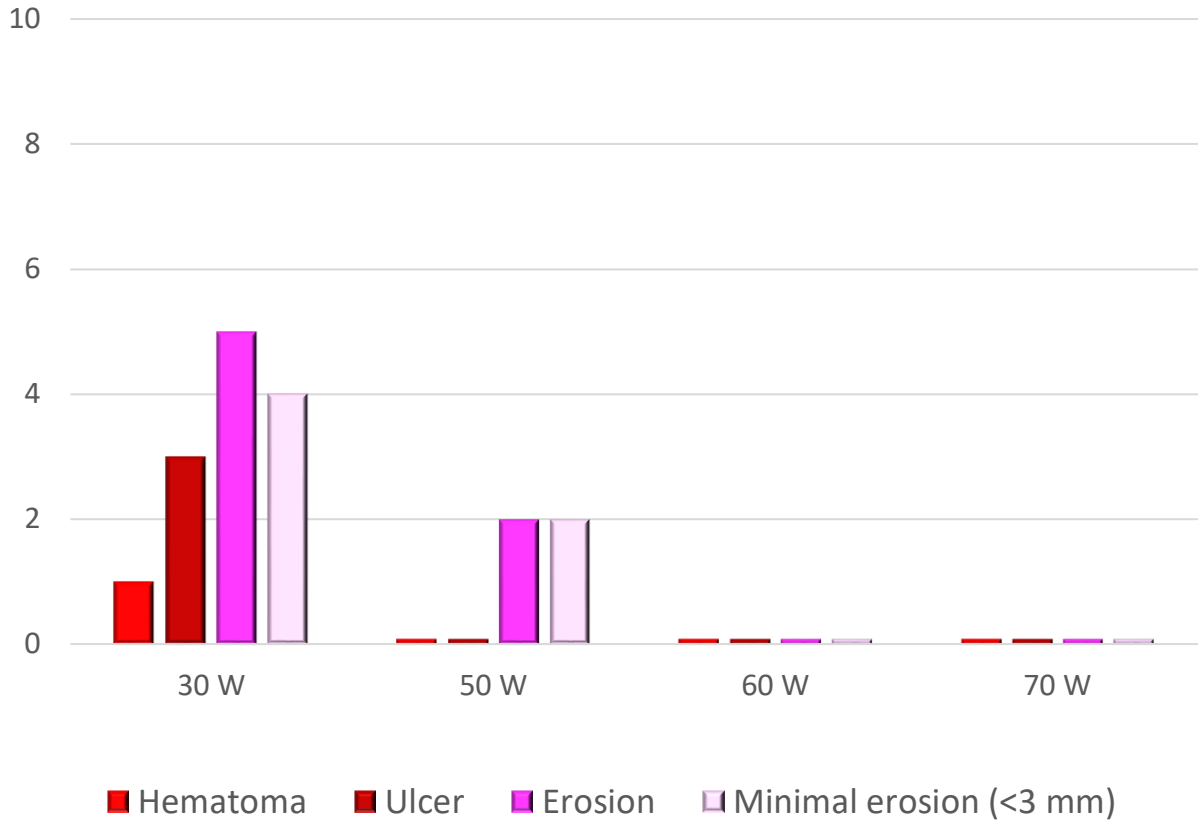
- **Esophageal endoscopy after ablation in all.**

Efficacy

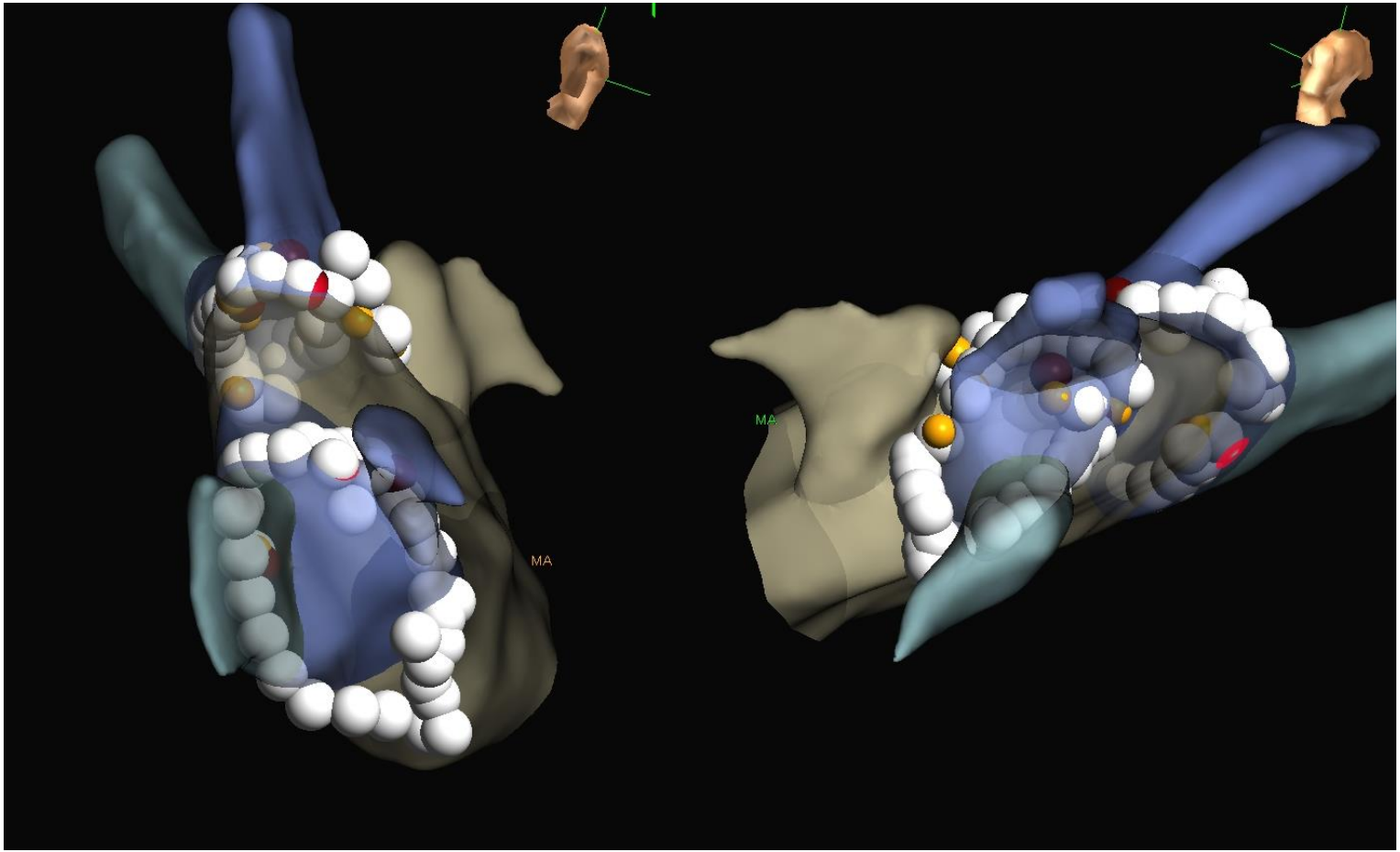
- First-pass PVI: Left PVs Right PVs
  - HPSD 50W: 56% 56%
  - HPSD 60W: 57% 60%
  - HPSD 70W: 85% 82%

p=0.038 p=0.13

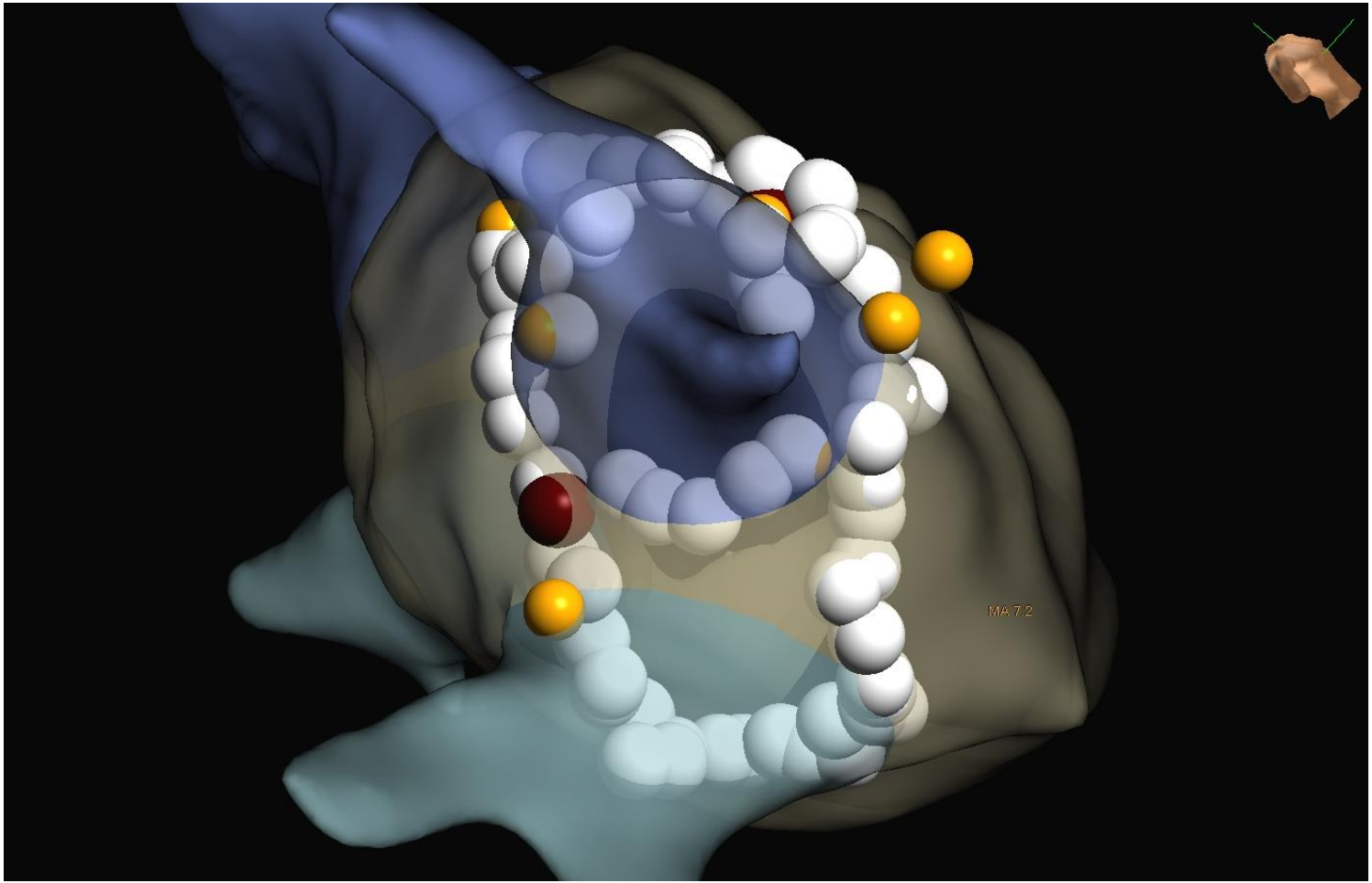
Safety



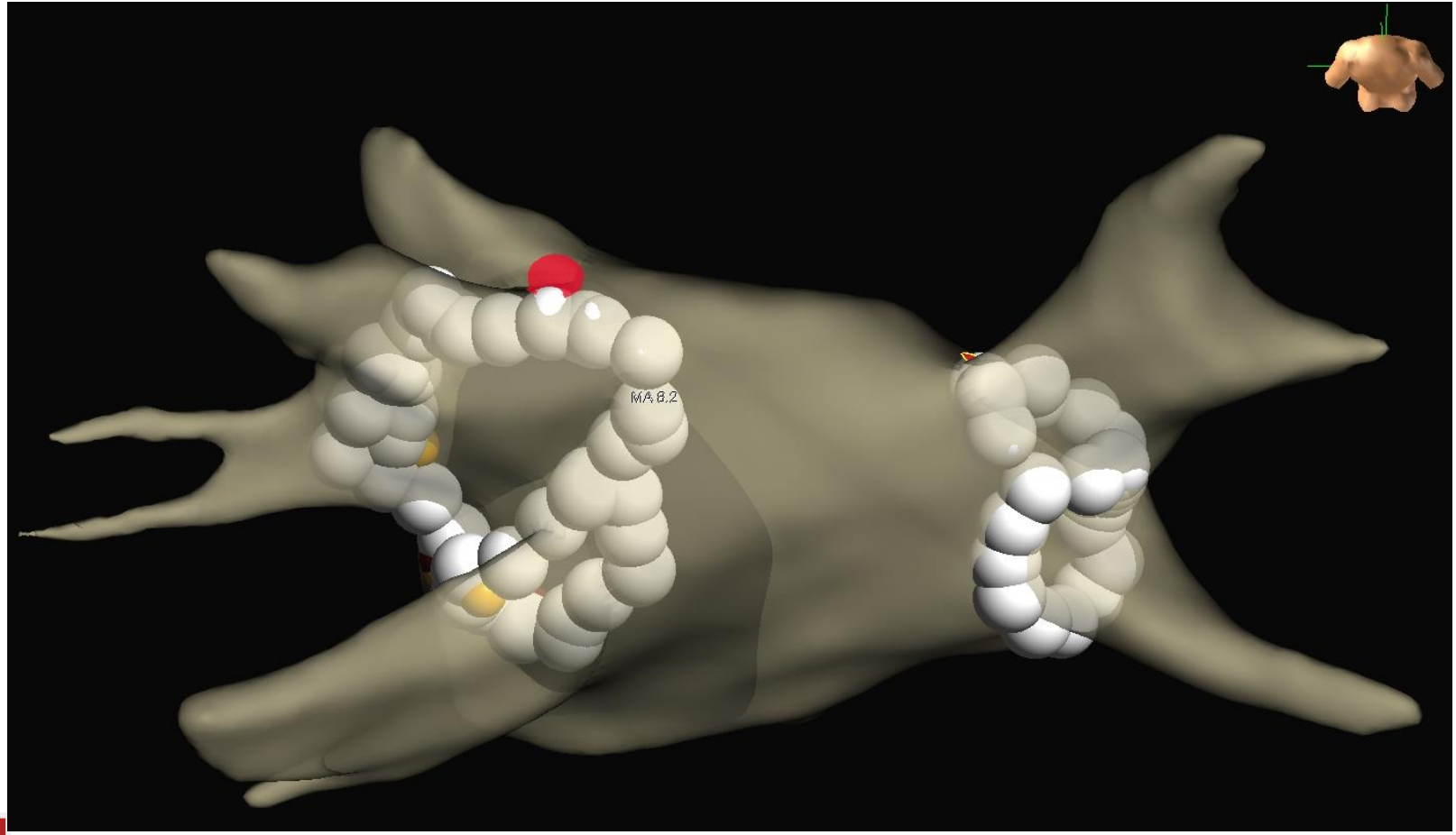
Pops: None in group 70 W



PRAGUE RHYTHM



PRAGUE RHYTHM



PRAGUE RHYTHM

ESC European Society of Cardiology

Europace (2021) **00**, 1–12
doi:10.1093/europace/euaa327

CLINICAL RESEARCH

High-power short duration vs. conventional radiofrequency ablation of atrial fibrillation: a systematic review and meta-analysis

Venkatesh Ravi [1], Abhushan Poudyal[2], Qurrat-Ul-Ain Abid[1], Timothy Larsen[1], Kousik Krishnan[1], Parikshit S. Sharma[1], Richard G. Trohman[1], and Henry D. Huang[1]*

[1]Section of Electrophysiology, Division of Cardiology, Department of Medicine, Rush University Medical Center, 1717 W Congress Pkwy Suite 317 Kellogg, Chicago, IL 60612, USA; and [2]Division of Cardiology, Department of Medicine, John H. Stroger Hospital of Cook County, Chicago, IL, USA

Received 4 July 2020; editorial decision 26 September 2020; accepted after revision 28 September 2020

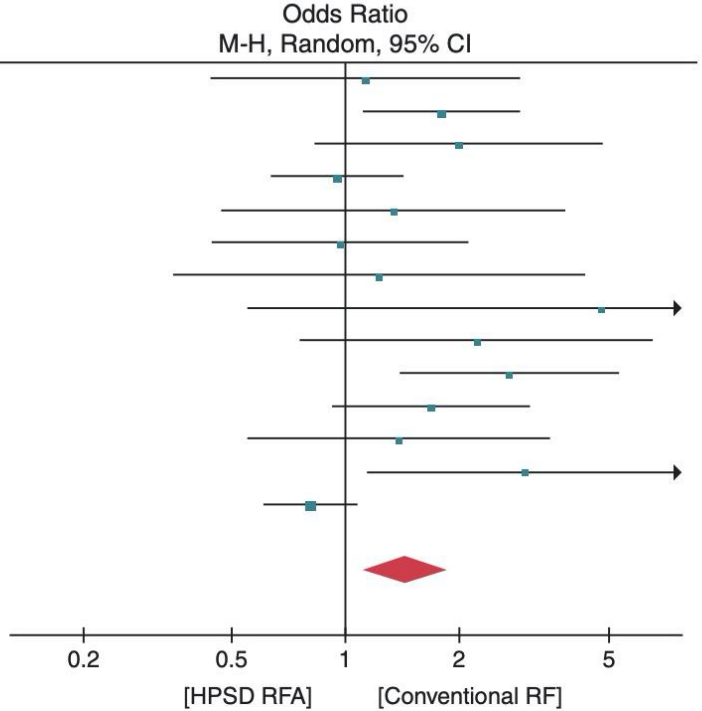
Study	*N*	Type of AF	RFA catheter	HPSD RFA strategy[a]
Nilsson *et al.* (2006)[7]	45 vs. 45	Paroxysmal + persistent	Irrigated	45 W, 55°C, 20 s
Winkle *et al.* (2011)[14]	666 vs. 76	Paroxysmal + persistent	Irrigated	50 W, 50°C, 3–10 s
Baher *et al.* (2018)[15]	574 vs. 113	Paroxysmal + persistent	Irrigated, CF and non-CF	50 W, 50°C, 5 s
Dhillon *et al.* (2018)[16]	50 vs. 50	Paroxysmal	Irrigated, CF	30 W posterior, 40 W elsewhere, AI 350–450
Pambrun *et al.* (2019)[17]	50 vs. 50	Paroxysmal	Irrigated, CF	40 W posterior, 50 W elsewhere, 2 s after signal modification
Berte *et al.* (2019)[18]	80 vs. 94	Paroxysmal + Persistent	Irrigated, CF	45 W anterior, 35 W posterior
Vassallo *et al.* (2019)[19]	41 vs. 35	Paroxysmal + persistent	Irrigated, CF	45–50 W CF 8–15/10–20 g, 6 s
Okamatsu *et al.* (2019)[20]	20 vs. 40	Paroxysmal + persistent	Irrigated, CF	50 W anterior, 40 W posterior 30 W oesophagus
Castrejón-Castrejón *et al.* (2019)[21]	48 vs. 47	Paroxysmal + persistent	Irrigated, CF	First 18 pts: 50 W ≤ 30 s. Last 30 pts: 60 W 2–3 s, then 7 s
Yazaki *et al.* (2019)[22]	32 vs. 32	Paroxysmal + persistent	Irrigated, CF	50 W, max temp 42°C, 5–10 s
Kottmaier *et al.* (2020)[23]	97 vs. 100	Paroxysmal	Irrigated	70 W, 7 s

AF freedom

A Freedom from atrial arrhythmia

Study or Subgroup	HPSD RFA Events	HPSD RFA Total	Conventional RFA Events	Conventional RFA Total	Weight	Odds Ratio M-H, Random, 95% CI	Year
Nilsson et al	34	45	33	45	5.6%	1.12 [0.44, 2.90]	2006
Winkle et al	386	666	33	76	11.2%	1.80 [1.11, 2.90]	2011
Dhillon et al	39	50	32	50	6.1%	1.99 [0.82, 4.83]	2018
Baher et al	333	574	67	113	12.3%	0.95 [0.63, 1.43]	2018
Yazaki et al	23	32	21	32	4.8%	1.34 [0.46, 3.87]	2019
Berte et al	66	80	78	94	7.0%	0.97 [0.44, 2.13]	2019
Pambrun et al	45	50	44	50	3.7%	1.23 [0.35 ,4.32]	2019
Okamatsu et al	19	20	32	40	1.5%	4.75 [0.55, 40.98]	2019
Vassalo et al	34	41	24	35	4.6%	2.23 [0.75, 6.57]	2019
Kottmaier et al	81	97	65	100	8.4%	2.73 [1.39, 5.36]	2020
Yavin et al	89	112	78	112	9.2%	1.69 [0.92, 3.11]	2020
Kyrikopolou et al	72	80	91	105	5.8%	1.38 [0.55, 3.48]	2020
Ejima et al	53	60	43	60	5.4%	2.99 [1.14, 7.88]	2020
Bunch et al	247	402	267	402	14.3%	0.81 [0.60, 1.08]	2020
Total (95% CI)		2309		1314	100.0%	1.44 [1.10, 1.90]	
Total events	1521		908				

Heterogeneity: $Tau^2 = 0.11$; $Chi^2 = 26.11$, df = 13 ($P = 0.02$); $I^2 = 50\%$
Test for overall effect: Z = 2.63 ($P = 0.009$)



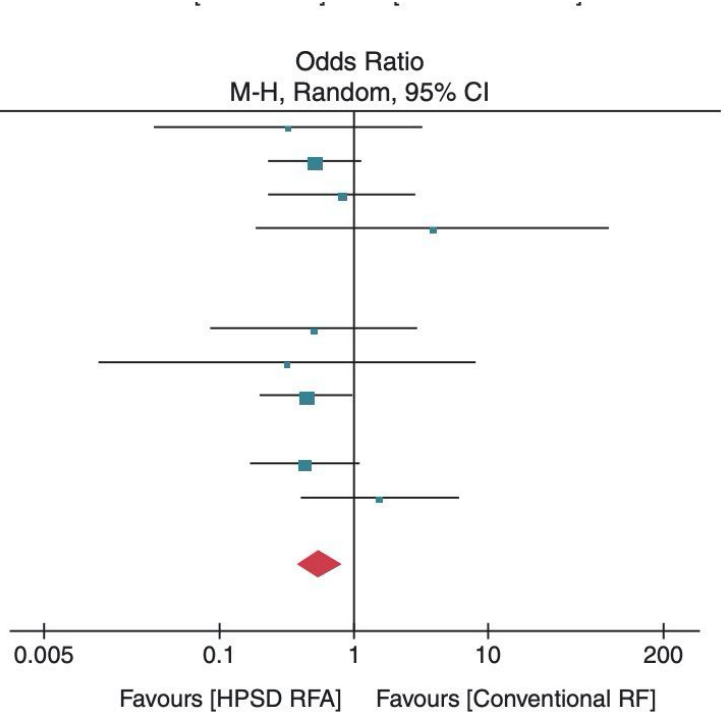
PRAGUE RHYTHM

Acute PV reconnection

B Acute pulmonary vein reconnection

Study or Subgroup	HPSD RFA Events	HPSD RFA Total	Conventional RFA Events	Conventional RFA Total	Weight	Odds Ratio M-H, Random, 95% CI	Year
Nilsson et al	1	45	3	46	3.1%	0.33 [0.03, 3.26]	2006
Dhillon et al	18	50	26	50	25.4%	0.52 [0.23, 1.16]	2018
Pambrun et al	5	50	6	50	10.3%	0.81 [0.23, 2.87]	2019
Okamatsu et al	20	20	37	40	1.8%	3.83 [0.19, 77.76]	2019
Berte et al	0	80	0	94		Not estimable	2019
Vassalo et al	0	41	0	35		Not estimable	2019
Yazaki et al	2	30	4	32	5.2%	0.50 [0.08, 2.95]	2019
Castrejon et al	0	48	1	47	1.6%	0.32 [0.01, 8.05]	2019
Ejima et al	37	60	47	60	25.2%	0.44 [0.20, 1.00]	2020
Bunch et al	0	402	0	402		Not estimable	2020
Yavin et al	7	112	15	112	18.5%	0.43 [0.17, 1.10]	2020
Kyrikopolou et al	5	80	4	97	9.0%	1.55 [0.40, 5.98]	2020
Total (95% CI)		1018		1065	100.0%	0.56 [0.38, 0.85]	
Total events	95		143				

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 5.09$, df = 8 ($P = 0.75$); $I^2 = 0\%$
Test for overall effect: Z = 2.78 ($P = 0.005$)



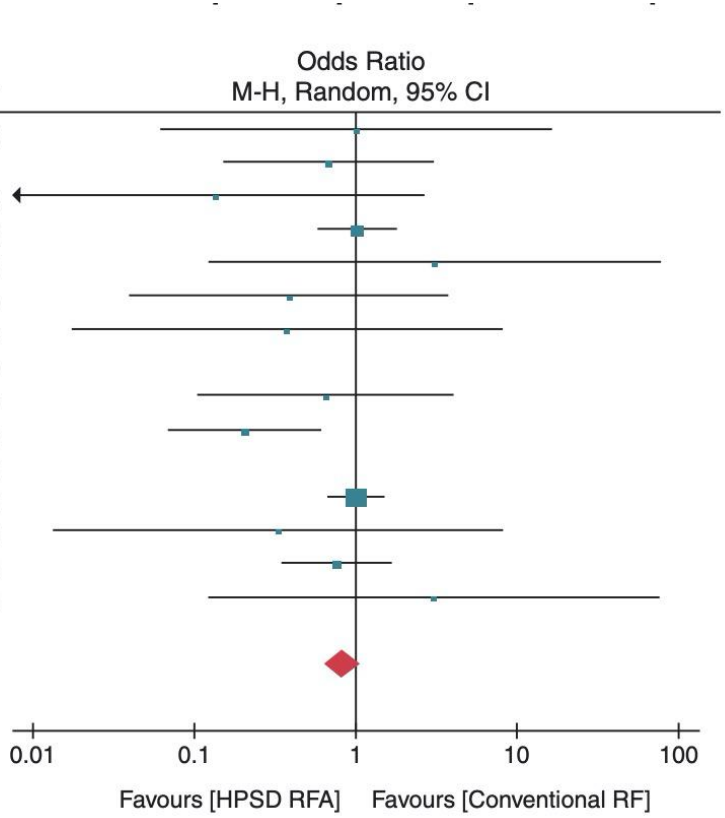
PRAGUE RHYTHM

Complications

C Total complications

Study or Subgroup	HPSD RFA Events	HPSD RFA Total	Conventional RFA Events	Conventional RFA Total	Weight	Odds Ratio M-H, Random, 95% CI	Year
Nilsson et al	1	45	3	45	1.0%	1.00 [0.06, 16.50]	2006
Winkle et al	12	666	2	76	3.3%	0.68 [0.15, 3.09]	2011
Dhillon et al	0	50	3	50	0.9%	0.13 [0.01, 2.67]	2018
Baher et al	82	574	16	113	22.9%	1.01 [0.57, 1.80]	2018
Yazaki et al	1	32	0	32	0.7%	3.10 [0.12, 78.87]	2019
Berte et al	1	80	3	94	1.5%	0.38 [0.04, 3.77]	2019
Okamatsu et al	0	20	2	40	0.8%	0.38 [0.02, 8.20]	2019
Vassalo et al	0	41	0	35		Not estimable	2019
Pambrun et al	2	50	3	50	2.3%	0.65 [0.10, 4.09]	2019
Castrejon et al	5	48	17	47	6.3%	0.21 [0.07, 0.62]	2019
Kyrikopolou et al	0	80	0	105		Not estimable	2020
Bunch et al	54	402	54	402	46.5%	1.00 [0.67, 1.50]	2020
Yavin et al	0	112	1	112	0.7%	0.33 [0.01, 8.20]	2020
Kottmaier et al	13	97	17	100	12.5%	0.76 [0.35, 1.65]	2020
Ejima et al	1	60	0	60	0.7%	3.05 [0.12, 76.39]	2020
Total (95% CI)		2357		1361	100.0%	0.83 [0.63, 1.09]	
Total events	172		119				

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 11.38$, df = 12 ($P = 0.50$); $I^2 = 0\%$
Test for overall effect: Z = 1.32 ($P = 0.19$)



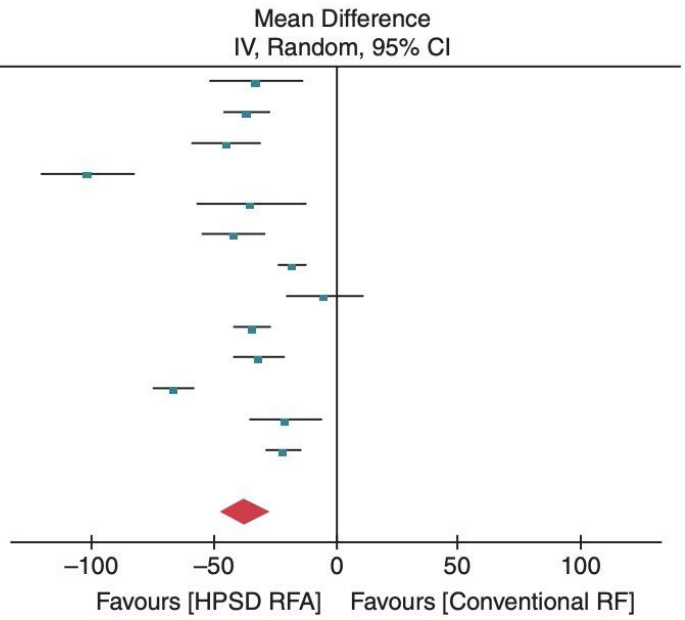
PRAGUE RHYTHM

Procedure duration

A Procedure duration

Study or Subgroup	HPSD RFA Mean	SD	Total	Conventional RFA Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Year
Nilsson et al	94	33	45	127	57	45	6.9%	−33.00 [−52.24, −13.76]	2006
Winkle et al	125.1	36.5	666	161.9	40	76	8.2%	−36.80 [−46.21, −27.39]	2011
Dhillon et al	156.4	34.7	50	201.7	36.9	50	7.6%	−45.30 [−59.34, −31.26]	2018
Baher et al	149	65	574	251	101	113	6.8%	−102.00 [−121.37, −82.63]	2018
Yazaki et al	115	32	32	150	57	32	6.3%	−35.00 [−57.65, −12.35]	2019
Vassalo et al	106	23	41	148	33.6	35	7.7%	−42.00 [−55.17, −28.83]	2019
Berte et al	82	18	80	100	22	94	8.5%	−18.00 [−23.94, −12.06]	2019
Castrejon et al	115	32	48	120	45	47	7.4%	−5.00 [−20.73, 10.73]	2019
Pambrun et al	73.1	18.2	50	107.4	21.2	50	8.3%	−34.30 [−42.04, −26.56]	2019
Kyrikopolou et al	91.4	17.2	80	123	51.1	105	8.1%	−31.60 [−42.09, −21.11]	2020
Bunch et al	104.3	63.6	402	170.8	59.2	402	8.3%	−66.50 [−74.99, −58.01]	2020
Ejima et al	119.3	28.1	60	140.1	51.2	60	7.5%	−20.80 [−35.58, −6.02]	2020
Kottmaier et al	89.5	23.9	97	111.2	27.9	100	8.4%	−21.70 [−28.95, −14.45]	2020
Total (95% CI)			2225			1209	100.0%	−37.35 [−48.30, −26.40]	

Heterogeneity: $Tau^2 = 358.67$; $Chi^2 = 162.68$, df = 112 ($P < 0.00001$); $I^2 = 93\%$
Test for overall effect: Z = 6.69 ($P < 0.00001$)



PRAGUE RHYTHM

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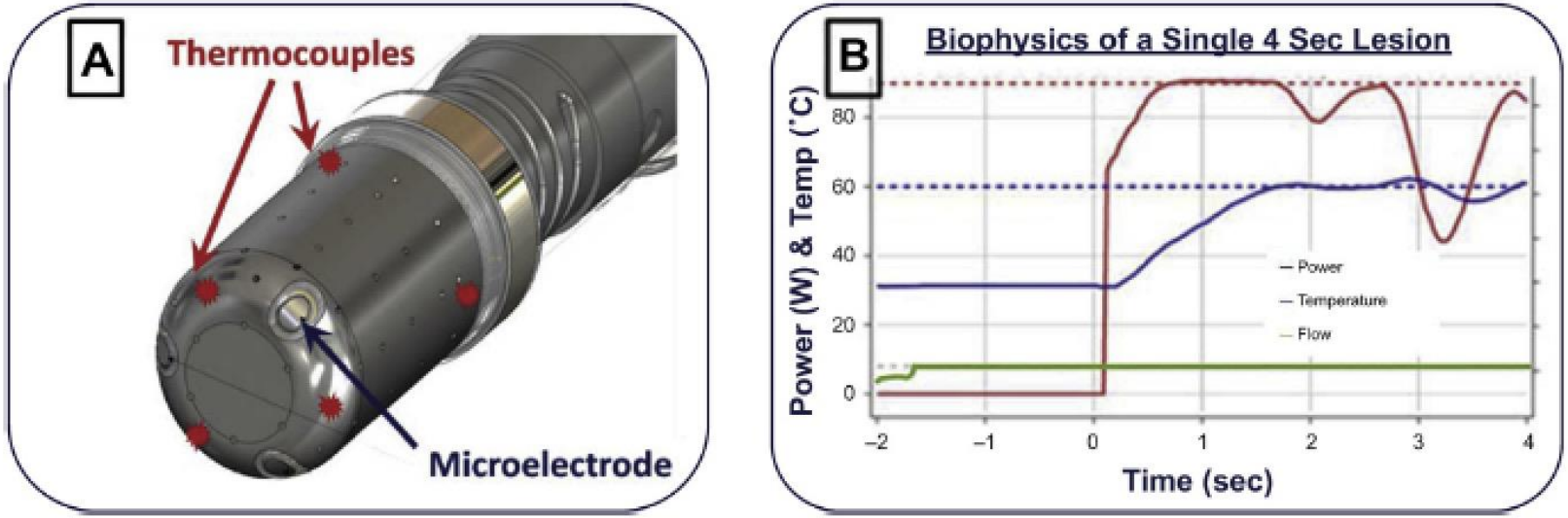
Pulmonary Vein Isolation With Very High Power, Short Duration, Temperature-Controlled Lesions

The QDOT-FAST Trial

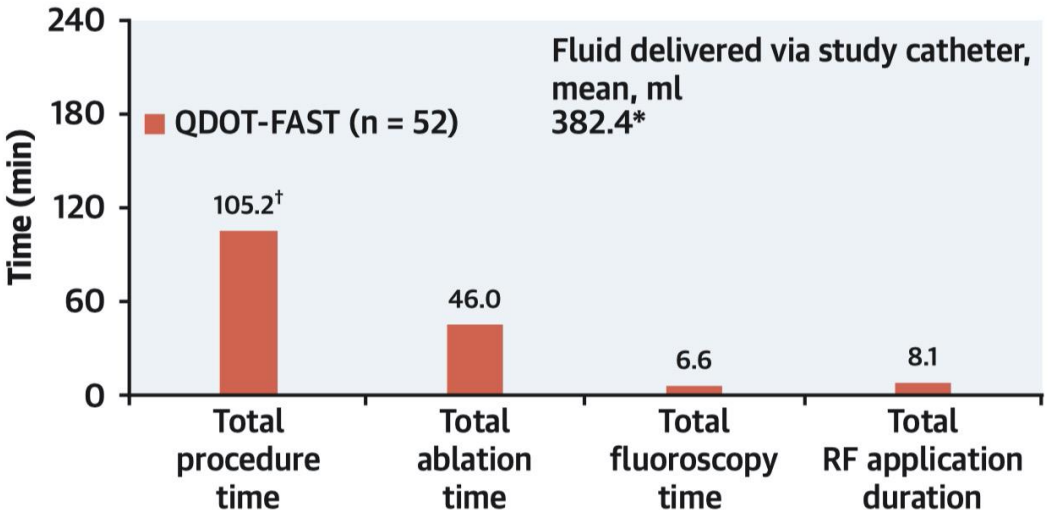
Vivek Y. Reddy, MD,[a,b] Massimo Grimaldi, MD,[c] Tom De Potter, MD,[d] Johan M. Vijgen, MD,[e] Alan Bulava, MD, PhD,[f] Mattias Francis Duytschaever, MD,[g] Martin Martinek, MD,[h] Andrea Natale, MD,[i] Sebastien Knecht, MD, PhD,[g] Petr Neuzil, MD, PhD,[b] Helmut Pürerfellner, MD[h]

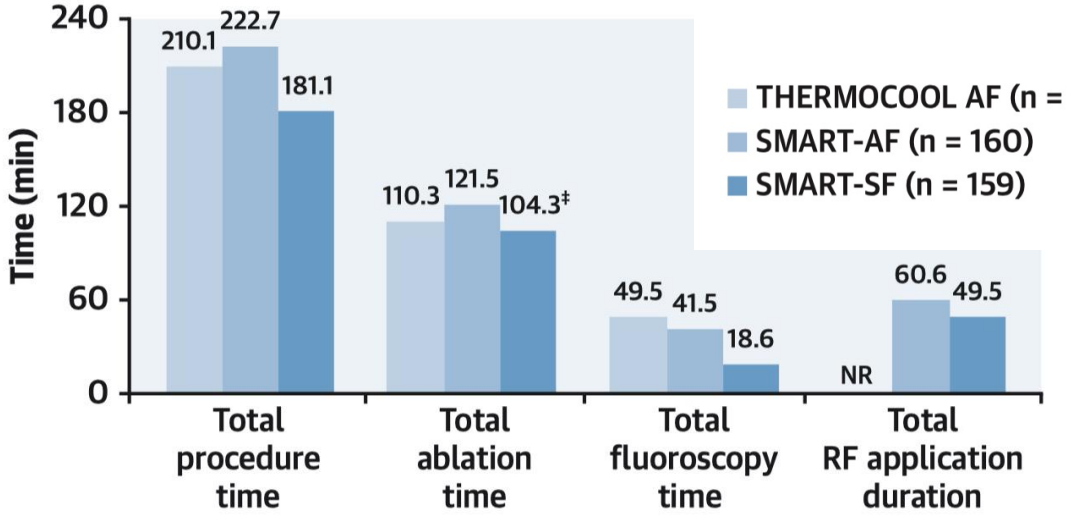
PRAGUE RHYTHM

FIGURE 1 The vHPSD Catheter



(A) The very high power-short duration (vHPSD) catheter tip is shown highlighting the microelectrodes and 6 thermocouples. **(B)** The biophysical parameters of an example ablation lesion is shown. This includes a 2-s pre-cooling phase, followed by a 4-s vHPSD ablation lesion. Note the power modulation that is particularly striking in the last 1.5 s of energy delivery to maintain the target temperature of 60°C.


240
180
120
60
0
Time (min)
QDOT-FAST (n = 52)
Fluid delivered via study catheter, mean, ml
382.4*
105.2†
46.0
6.6
8.1
Total procedure time
Total ablation time
Total fluoroscopy time
Total RF application duration


240
180
120
60
0
Time (min)
210.1
222.7
181.1
110.3
121.5
104.3‡
49.5
41.5
18.6
NR
60.6
49.5
THERMOCOOL AF (n = 139)
SMART-AF (n = 160)
SMART-SF (n = 159)
Fluid delivered via study catheter, mean, mL
1624.9
1879.6
898.4
Total procedure time
Total ablation time
Total fluoroscopy time
Total RF application duration

Take Home Message

1. HPSD appears to be safe and effective
2. Reduction of the RF and procedure times
3. Best settings or the need to adjust power according to different LA areas still need to be defined.

PRAGUE RHYTHM

Thank you!!

@joselmerino

jlmerino@arritmias.net

PRAGUE RHYTHM