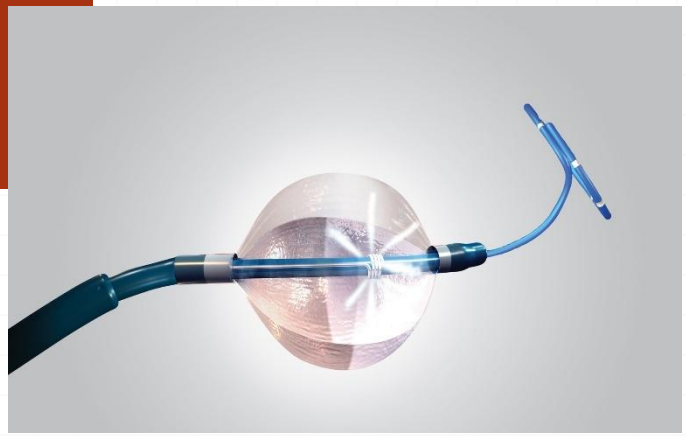
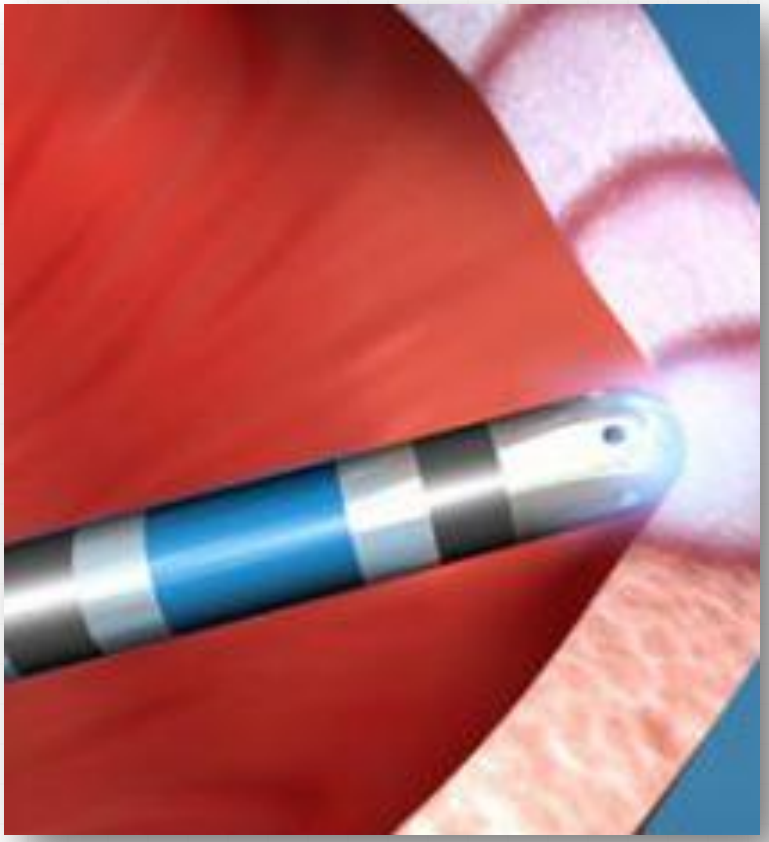
New Technology for Complete & Permanent PV Isolation

Keimyung University Dongsan Medical Center
Hyoung-Seob Park

New Technology for PV Isolation



Contact-Force Sensing Catheters



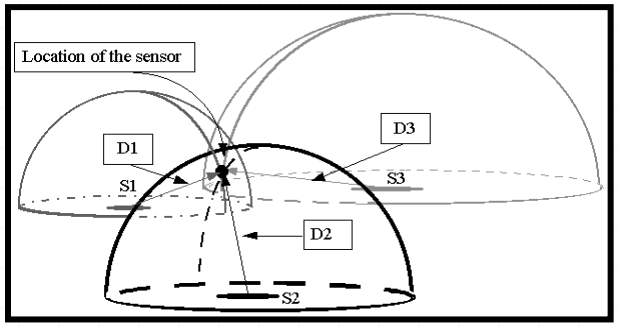
TactiCath™ Quartz Catheter
(Endosense/St. Jude Medical)

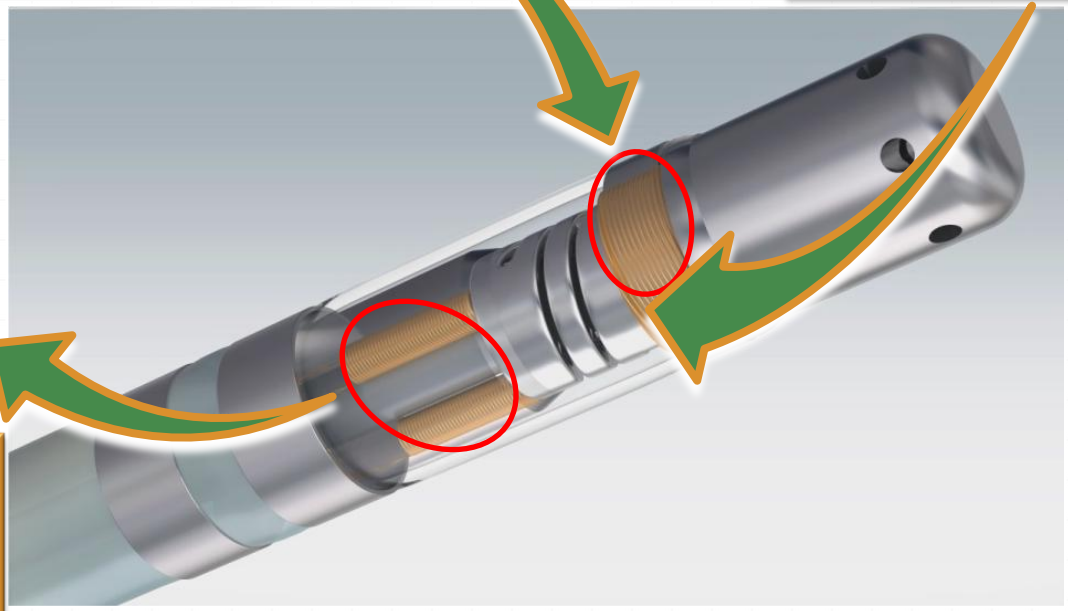
THERMOCOOL® SMARTTOUCH™ Catheter
(Biosense Webster)

THERMOCOOL® SMARTTOUCH™ Catheter

TRANSMITTER coil in the tip sends location reference signal about the Spring.

PRECISION SPRING allows small amount of electrode deflection.





SENSORS monitors the transmitter coils location signal and records the micro-movements of the spring.

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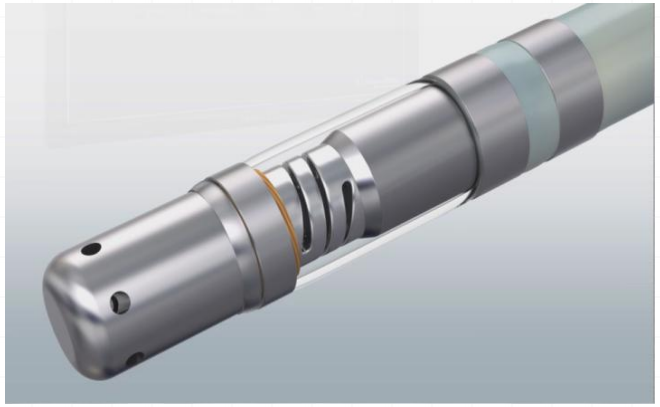
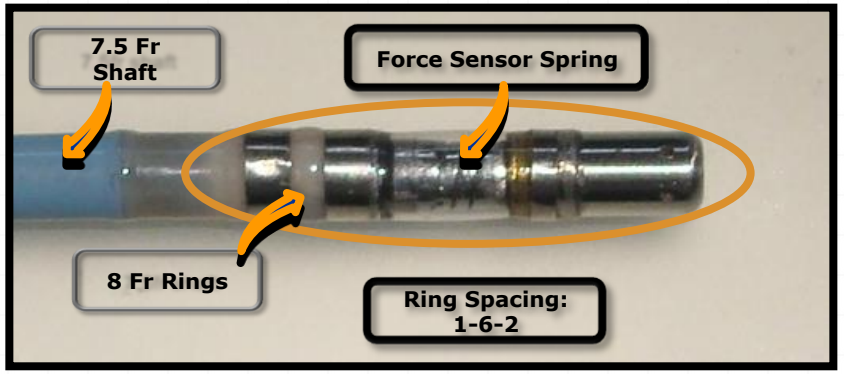
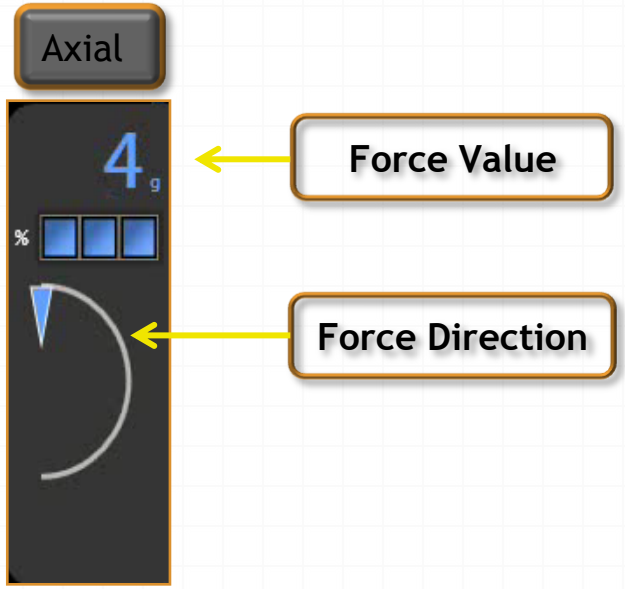
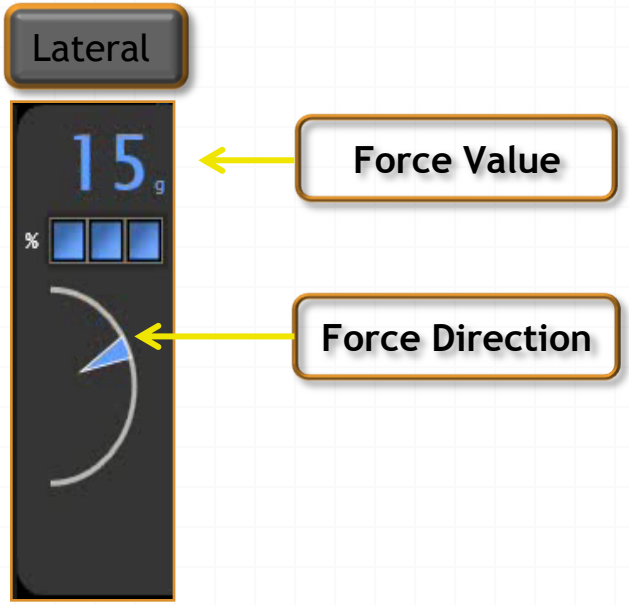
THERMOCOOL® SMARTTOUCH™ Catheter

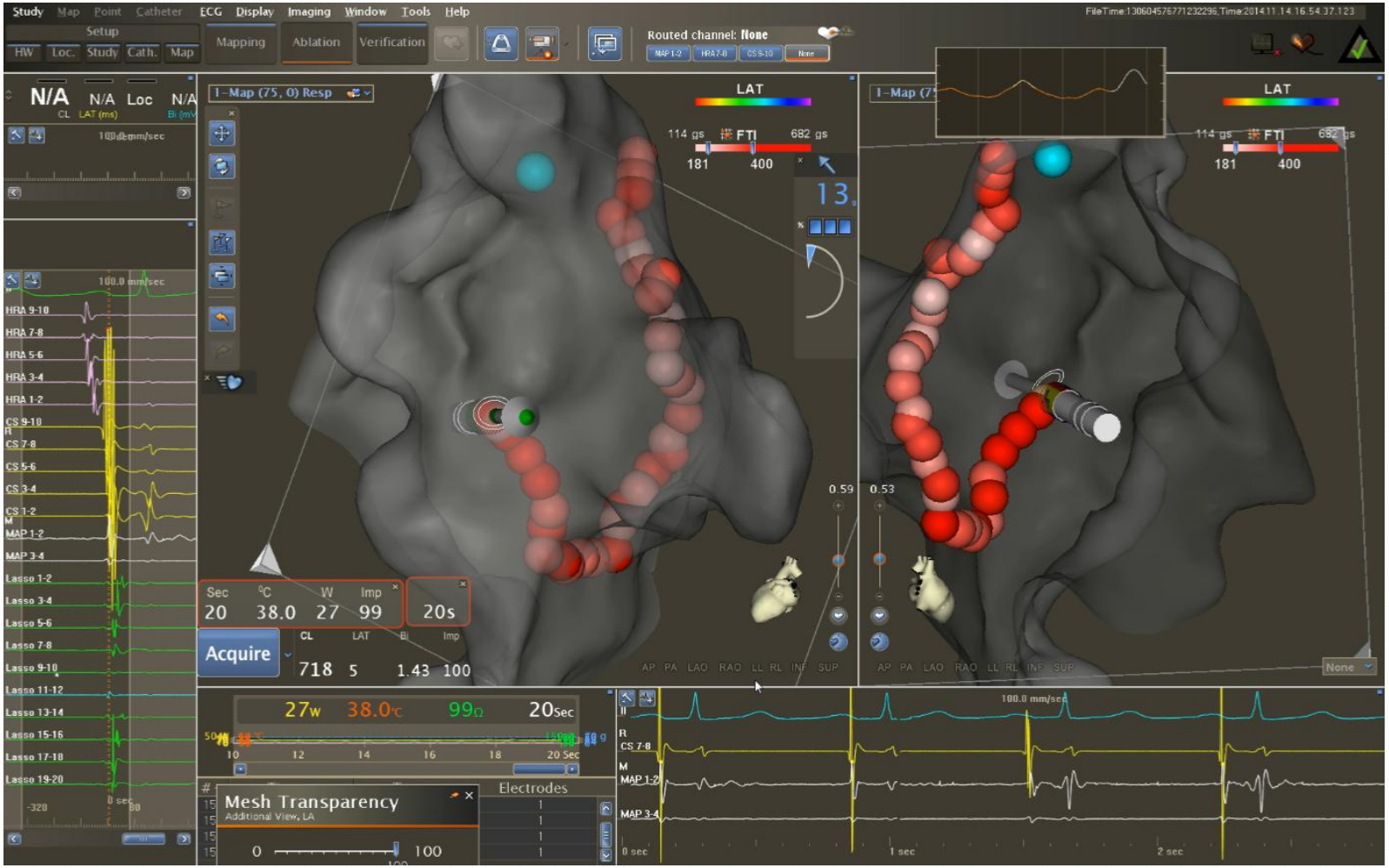








AF Ablation with CF and VISITAG™ Module



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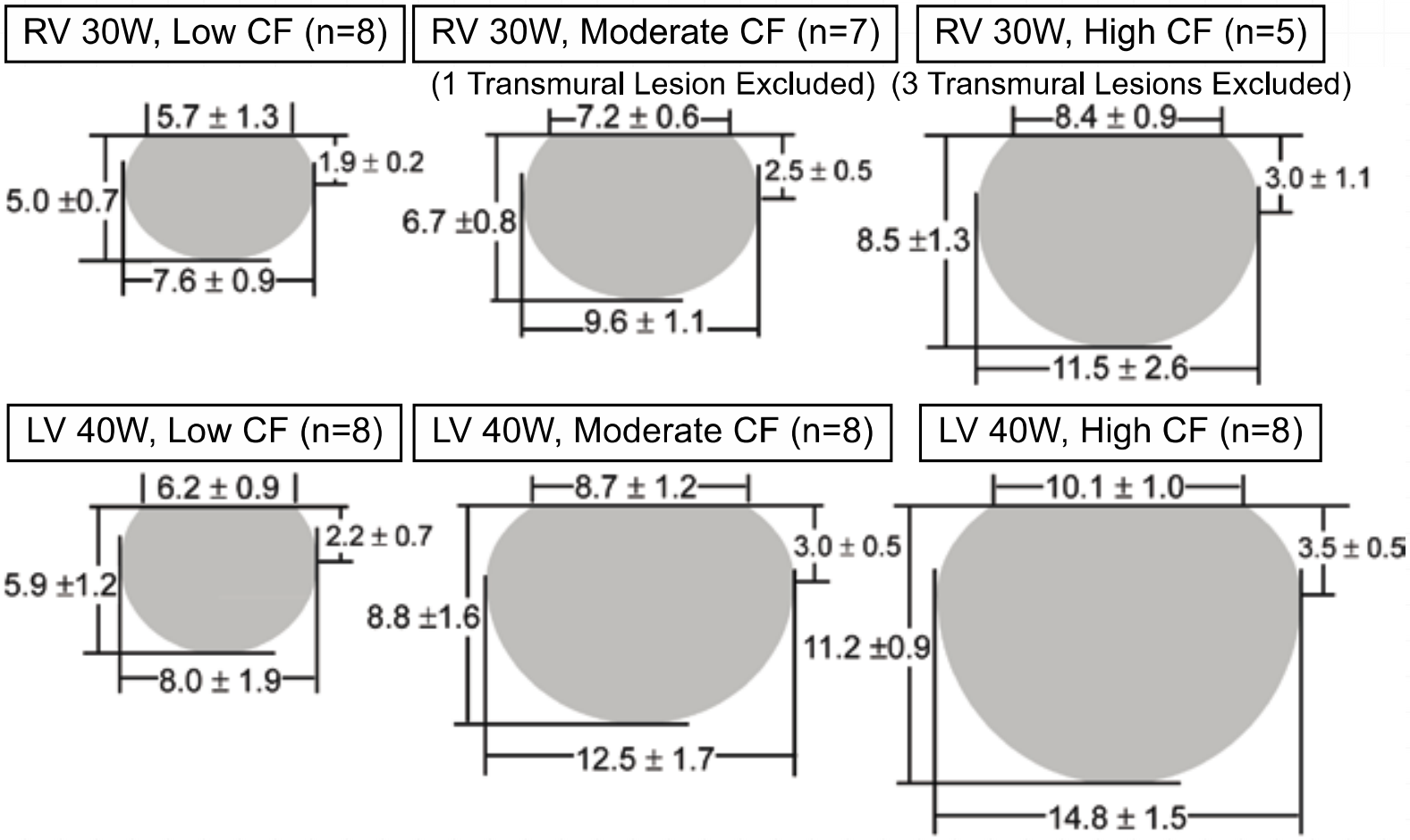
Contact Force and Lesion Size



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Ikeda A et al. Circ Arrhythm Electrophysiol. 2014;7(6):1174-80.

Multicenter SMART-AF Trial

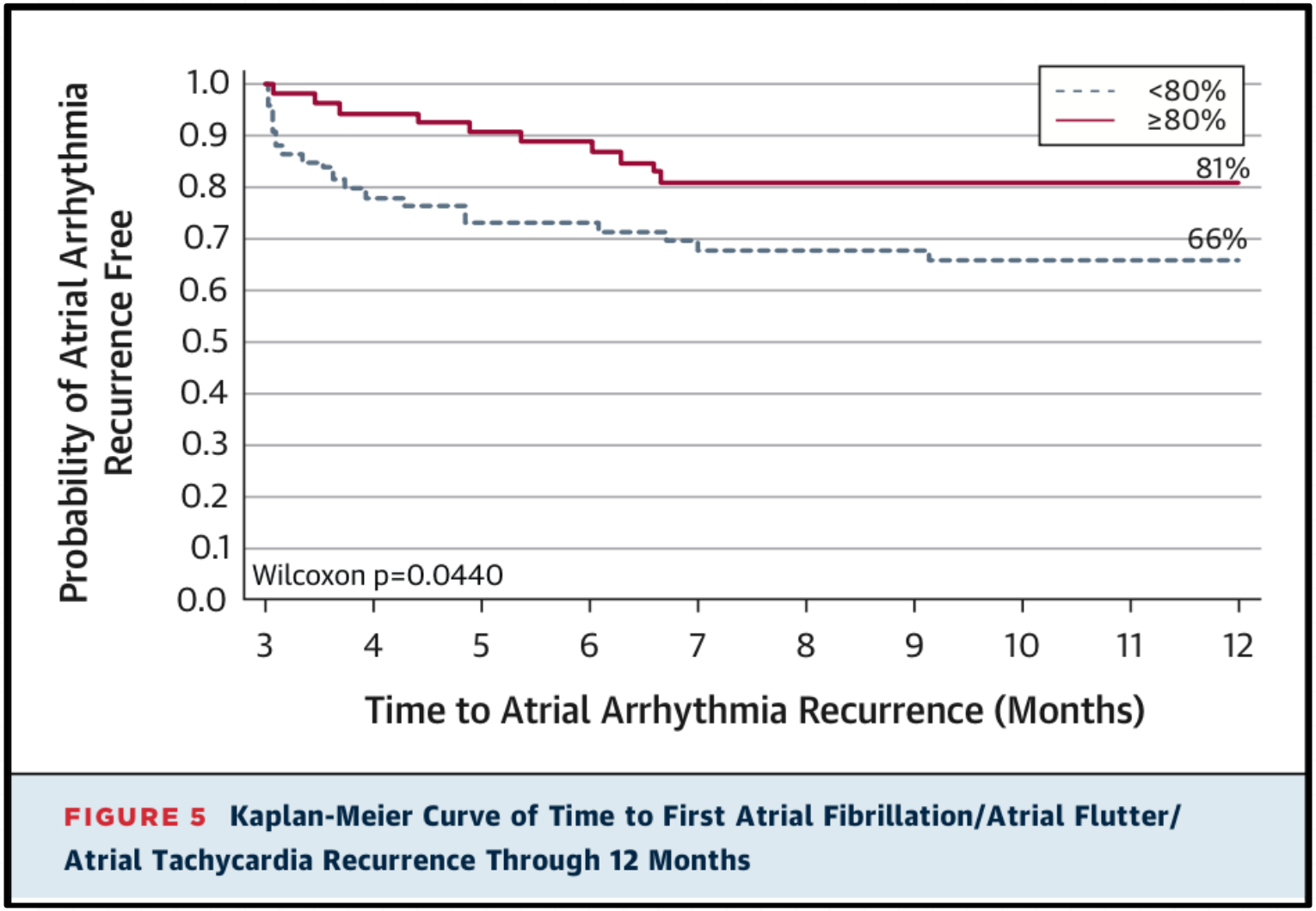

FIGURE 5 Kaplan-Meier Curve of Time to First Atrial Fibrillation/Atrial Flutter/Atrial Tachycardia Recurrence Through 12 Months

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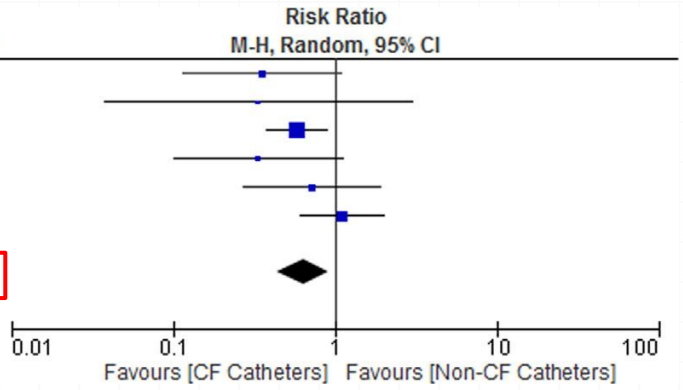
Natale A et al. J Am Coll Cardiol. 2014;64(7):647-56.

Reduction in AF recurrence : Meta-Analysis

Study or Subgroup	CF Catheters Events	Total	Non-CF Catheters Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Andrade et al 2014	3	25	17	50	9.4%	0.35 [0.11, 1.09]
Kimura et al 2014	1	19	3	19	2.7%	0.33 [0.04, 2.93]
Mansour et al 2014 (Abstract)	20	83	60	143	40.8%	0.57 [0.37, 0.88]
Marijon et al 2014	3	30	9	30	8.4%	0.33 [0.10, 1.11]
Sciarra et al 2014	5	21	7	21	12.2%	0.71 [0.27, 1.89]
Wakili et al 2014	13	32	13	35	26.4%	1.09 [0.60, 1.99]
Total (95% CI)		**210**		**298**	**100.0%**	**0.63 [0.44, 0.91]**
Total events	45		109			

Heterogeneity: Tau² = 0.04; Chi² = 6.06, df = 5 (P = 0.30); I² = 18%

Test for overall effect: Z = 2.49 (P = 0.01)



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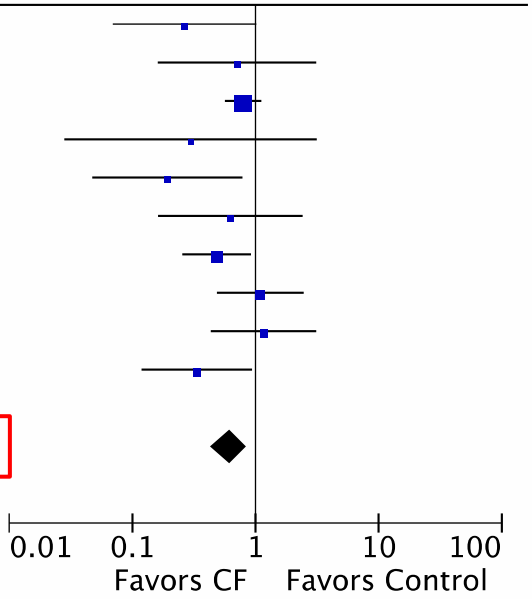
Afzal MR et al. Heart Rhythm. 2015;12:1990-6.

Reduction in AF recurrence : Meta-Analysis

Study or Subgroup	CF Events	CF Total	Control Events	Control Total	Weight	Odds Ratio M-H, Random, 95% CI
Andrade	3	25	17	50	5.3%	0.26 [0.07, 1.01]
Casella	3	20	7	35	4.5%	0.71 [0.16, 3.10]
Jarman	100	200	223	400	31.5%	0.79 [0.56, 1.12]
Kimura	1	19	3	19	1.9%	0.30 [0.03, 3.14]
Marijon	3	30	11	30	4.9%	0.19 [0.05, 0.78]
Sciarra	5	21	7	21	5.3%	0.63 [0.16, 2.42]
Sigmund	20	99	34	99	16.9%	0.48 [0.25, 0.92]
Ullah	32	50	31	50	12.2%	1.09 [0.48, 2.45]
Wakili	13	32	13	35	9.1%	1.16 [0.43, 3.10]
Wutzler	5	31	41	112	8.4%	0.33 [0.12, 0.93]
Total (95% CI)		**527**		**851**	**100.0%**	**0.62 [0.45, 0.86]**
Total events	185		387			

Heterogeneity: $Tau^2 = 0.06$; $Chi^2 = 11.66$, df = 9 (P = 0.23); $I^2 = 23\%$

Test for overall effect: Z = 2.85 (P = 0.004)



35.1% vs. 45.5%

CF Range : 2-60 g (mean 17 ± 5 g)

Shurrab M et al. J Am Heart Assoc. 2015

Procedure time & Ablation Time: Meta Analysis

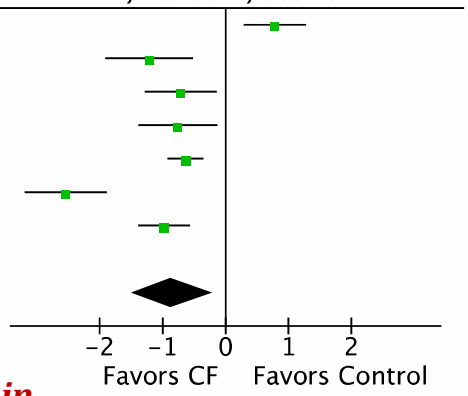
A

Study or Subgroup	CF Mean	CF SD	CF Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Andrade	235	90	25	179	59	50	14.6%	0.78 [0.29, 1.28]
Kimura	59	16	19	96	39	19	13.4%	-1.22 [-1.91, -0.52]
Martinek	154	39	25	185	46	25	14.1%	-0.72 [-1.29, -0.14]
Sciarra	140	53	21	181	53	21	13.8%	-0.76 [-1.39, -0.13]
Sigmund	192	53	99	226	53	99	15.5%	-0.64 [-0.92, -0.35]
Wakili	78	7	32	96	7	35	13.7%	-2.54 [-3.19, -1.89]
Wutzler	128	29	31	158	31	112	15.0%	-0.98 [-1.39, -0.56]
Total (95% CI)			**252**			**361**	**100.0%**	**-0.85 [-1.48, -0.21]**

Heterogeneity: $Tau^2 = 0.65$; $Chi^2 = 68.76$, df = 6 ($P < 0.00001$); $I^2 = 91\%$

Test for overall effect: $Z = 2.62$ ($P = 0.009$)

Std. Mean Difference IV, Random, 95% CI



156 min vs. 173 min

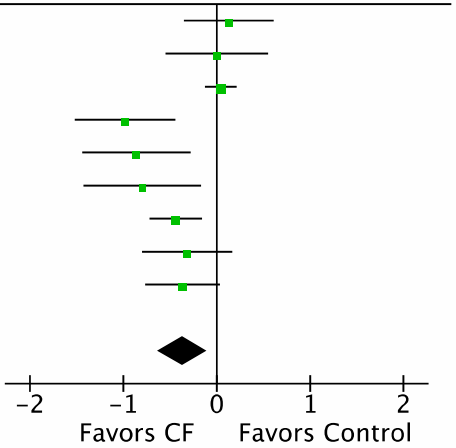
B

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Andrade	59	22	25	56	24	50	10.7%	0.13 [-0.35, 0.61]
Casella	34	11	20	34	12	35	9.6%	0.00 [-0.55, 0.55]
Jarman	55	23	200	54	24	400	15.6%	0.04 [-0.13, 0.21]
Marijon	45	18	30	65	22	30	9.8%	-0.98 [-1.52, -0.44]
Martinek	39	11	25	51	16	25	9.2%	-0.86 [-1.44, -0.28]
Sciarra	30	14	21	41	13	21	8.5%	-0.80 [-1.43, -0.17]
Sigmund	44	16	99	52	20	99	14.0%	-0.44 [-0.72, -0.16]
Wakili	31	4	32	32	2	35	10.7%	-0.32 [-0.80, 0.17]
Wutzler	39	13	31	45	17	112	12.0%	-0.37 [-0.77, 0.03]
Total (95% CI)			**483**			**807**	**100.0%**	**-0.36 [-0.62, -0.10]**

Heterogeneity: $Tau^2 = 0.11$; $Chi^2 = 30.33$, df = 8 ($P = 0.0002$); $I^2 = 74\%$

Test for overall effect: $Z = 2.71$ ($P = 0.007$)

Std. Mean Difference IV, Random, 95% CI



47 min vs. 51 min

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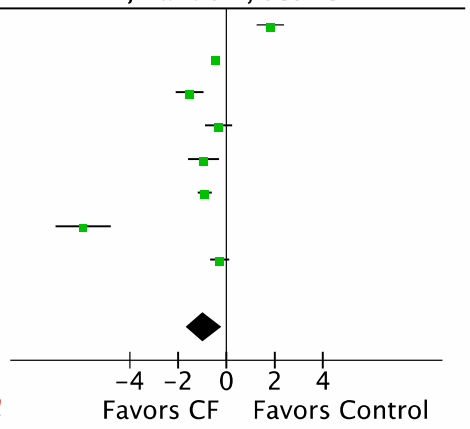
Fluoroscopic Time: Meta-Analysis

Study or Subgroup	CF Mean	CF SD	CF Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Andrade	72	19	25	37	19	50	12.6%	1.82 [1.26, 2.39]
Jarman	27	15	200	35	19	400	13.5%	-0.45 [-0.62, -0.28]
Marijon	20	4	30	27	5	30	12.5%	-1.53 [-2.11, -0.95]
Martinek	24	13	25	29	17	25	12.6%	-0.33 [-0.88, 0.23]
Sciarra	20	10	21	34	18	21	12.3%	-0.94 [-1.58, -0.30]
Sigmund	20	9	99	29	11	99	13.3%	-0.89 [-1.18, -0.60]
Wakili	33	3	32	51	3	35	10.2%	-5.93 [-7.07, -4.79]
Wutzler	40	11	31	44	15	112	13.1%	-0.28 [-0.68, 0.12]
Total (95% CI)			**463**			**772**	**100.0%**	**-0.94 [-1.66, -0.21]**

Heterogeneity: $Tau^2 = 1.01$; $Chi^2 = 174.22$, df = 7 ($P < 0.00001$); $I^2 = 96\%$

Test for overall effect: Z = 2.54 (P = 0.01)

28 min vs. 36 min



Shurrab M et al. J Am Heart Assoc. 2015

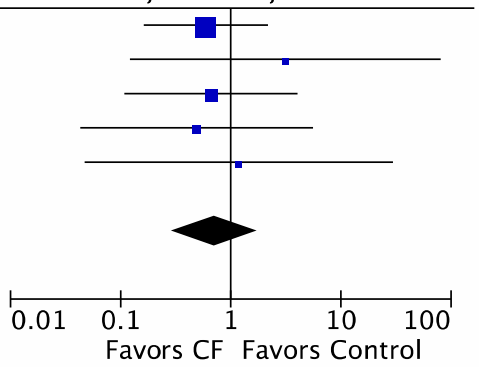
Complication Rate: Meta-Analysis

A Major Complications

Study or Subgroup	CF Events	CF Total	Control Events	Control Total	Weight	Odds Ratio M-H, Random, 95% CI
Jarman	3	200	10	400	47.0%	0.59 [0.16, 2.18]
Martinek	1	25	0	25	7.6%	3.12 [0.12, 80.39]
Sigmund	2	99	3	99	24.3%	0.66 [0.11, 4.04]
Ullah	1	50	2	50	13.5%	0.49 [0.04, 5.58]
Wutzler	0	31	1	112	7.7%	1.18 [0.05, 29.68]
Total (95% CI)		**405**		**686**	**100.0%**	**0.71 [0.29, 1.73]**
Total events	7		16			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.06$, df = 4 (P = 0.90); $I^2 = 0\%$

Test for overall effect: Z = 0.75 (P = 0.45)



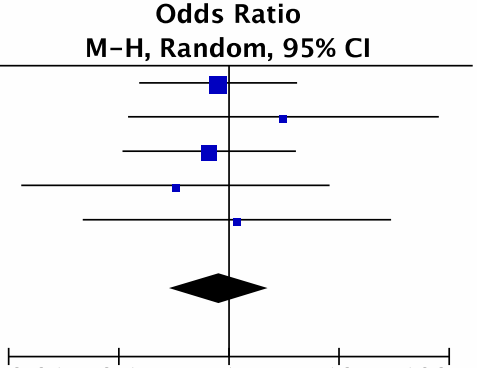
1.3% vs. 1.9%

B Cardiac Tamponade

Study or Subgroup	CF Events	CF Total	Control Events	Control Total	Weight	Odds Ratio M-H, Random, 95% CI
Jarman	2	200	5	400	38.3%	0.80 [0.15, 4.15]
Martinek	1	25	0	25	9.9%	3.12 [0.12, 80.39]
Sigmund	2	99	3	99	31.8%	0.66 [0.11, 4.04]
Ullah	0	50	1	50	10.0%	0.33 [0.01, 8.21]
Wutzler	0	31	1	112	10.0%	1.18 [0.05, 29.68]
Total (95% CI)		**405**		**686**	**100.0%**	**0.82 [0.29, 2.27]**
Total events	5		10			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.07$, df = 4 (P = 0.90); $I^2 = 0\%$

Test for overall effect: Z = 0.39 (P = 0.70)



1.2% vs. 1.4%

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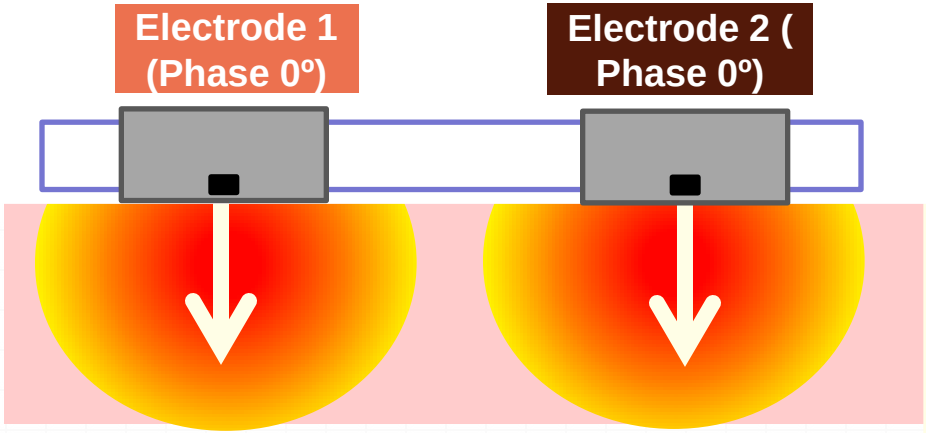
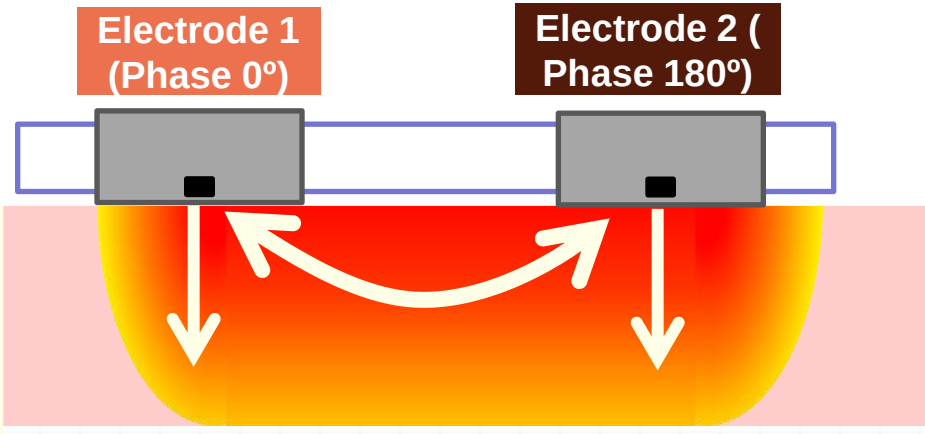
Phased RF Ablation

Energy Deployment - Phasing

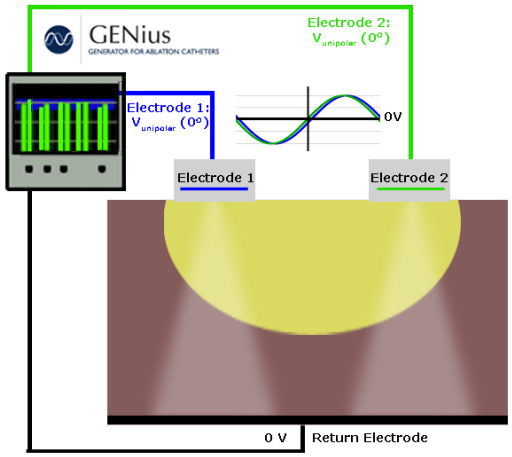
Unipolar for Depth & Bipolar for Continuity

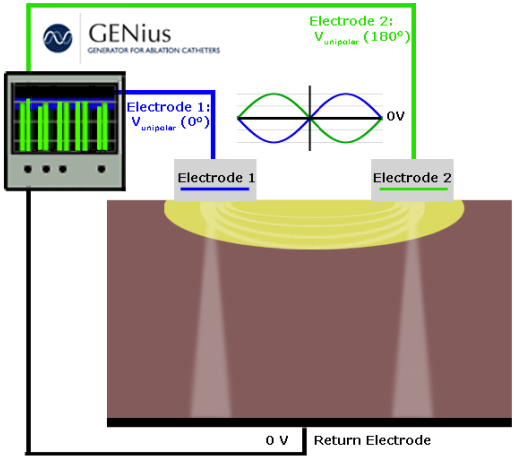


Unipolar Only



Unipolar and Bipolar





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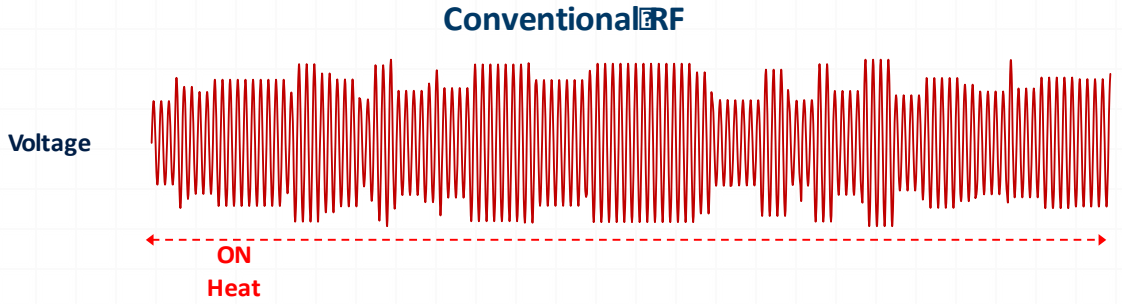
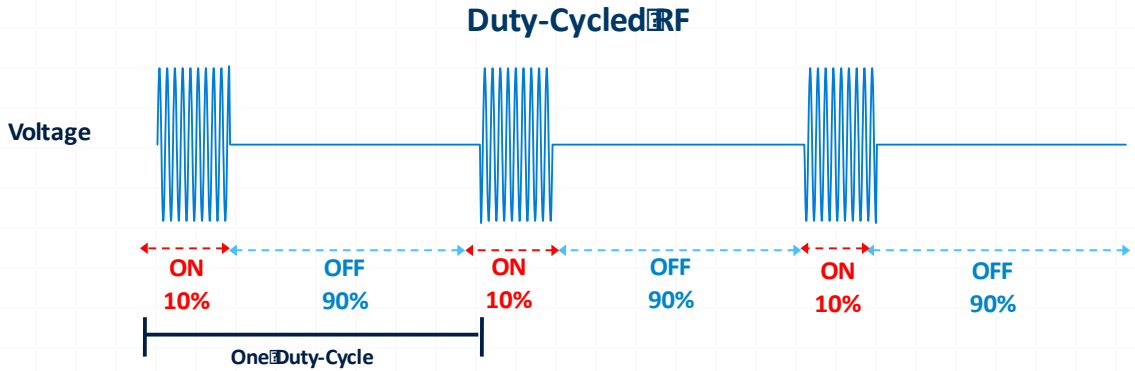
Duty-Cycling
Electrode Colling and Temperatur Measurement

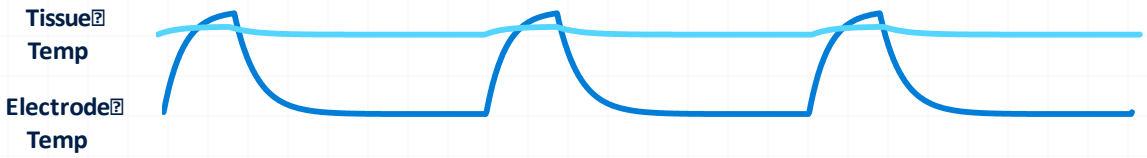
In conventional RF, power is continuously delivered and saline cooling is required to deliver enough power



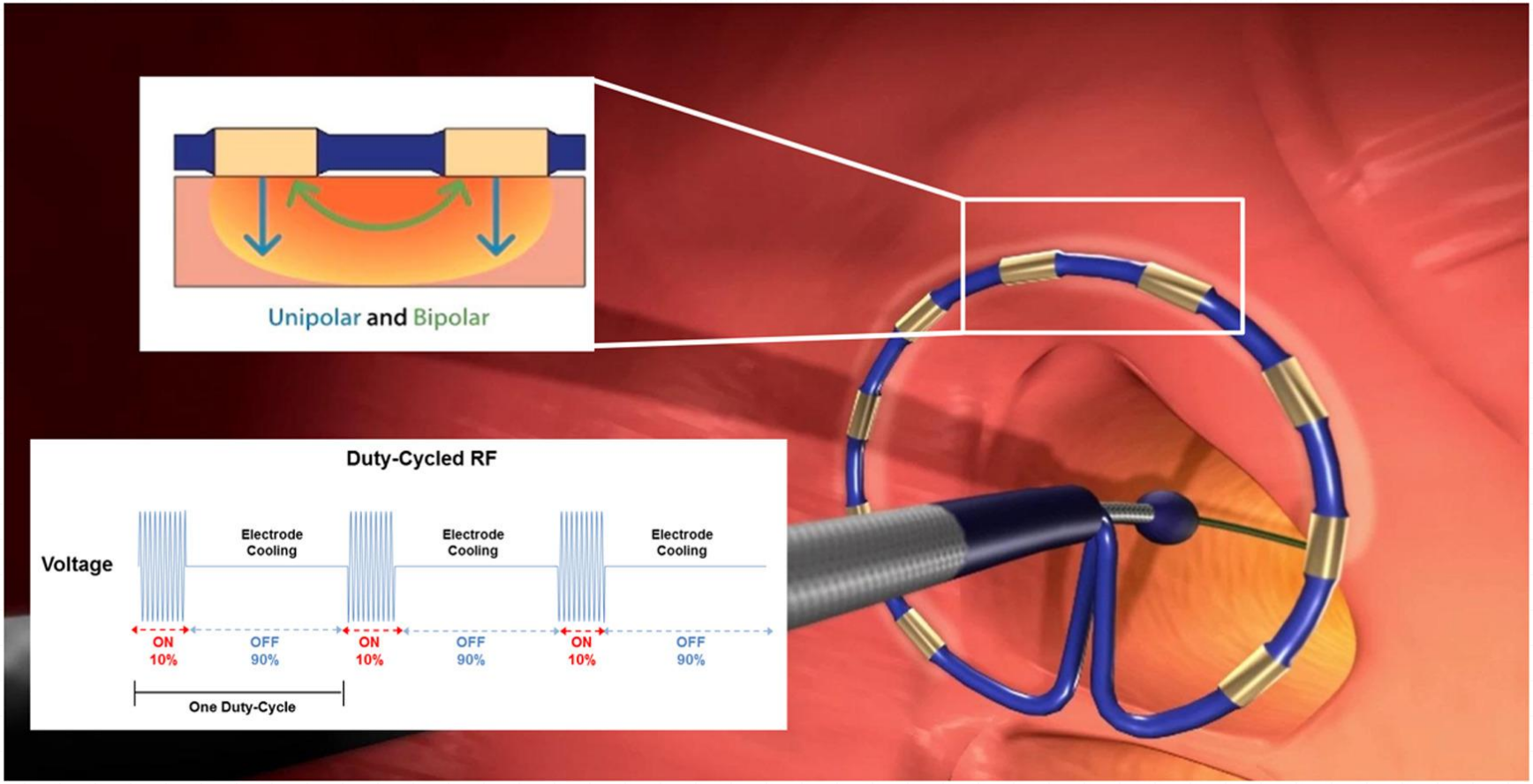
In Phased RF, 100W is delivered up to 10% of the time, permitting sufficient energy delivery while allowing electrodes to cool in the off period.



During the 'off' period, electrodes cool while tissue temperature remains close to target allowing lesion to progress

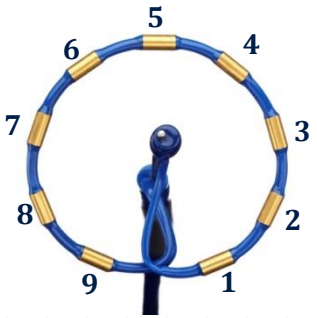
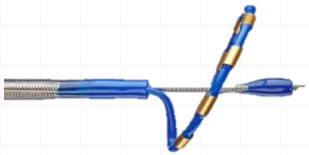


Phased RF Ablation



PVAC GOLD Summary

- Gold thermal conductivity allows more uniform heating and faster cooling than platinum providing the potential for precise temperature control across the electrode
- Eliminate 1:10 electrode interaction
- Should generate equivalently deep lesions to platinum because of gold's ability to deliver energy more efficiently and consistently
- Potential for improved uniformity of tissue contact
- Over-the-wire design should provide stability in various anatomies

Gold	Platinum
	
9 Electrodes	10 Electrodes
	
3.75mm Spacing	3mm Spacing
	
20° Forward Tilt	Perpendicular

Better Contact	Better Cooling	Better Lesions

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Phased RF Ablation Technology

- PVAC GOLD, MASC, and MAAC Catheters
  - Single transseptal access with 3 catheter system that allows mapping, ablation, and pacing through all or selected bipolar pairs

PVAC GOLD

MASC

MAAC

- GENius with ContactIQ Multichannel RF Generator
  - ContactIQ provides a display of effective contact and ablation progress
  - 16 independent temperature-controlled channels deliver unipolar and bipolar energy simultaneously

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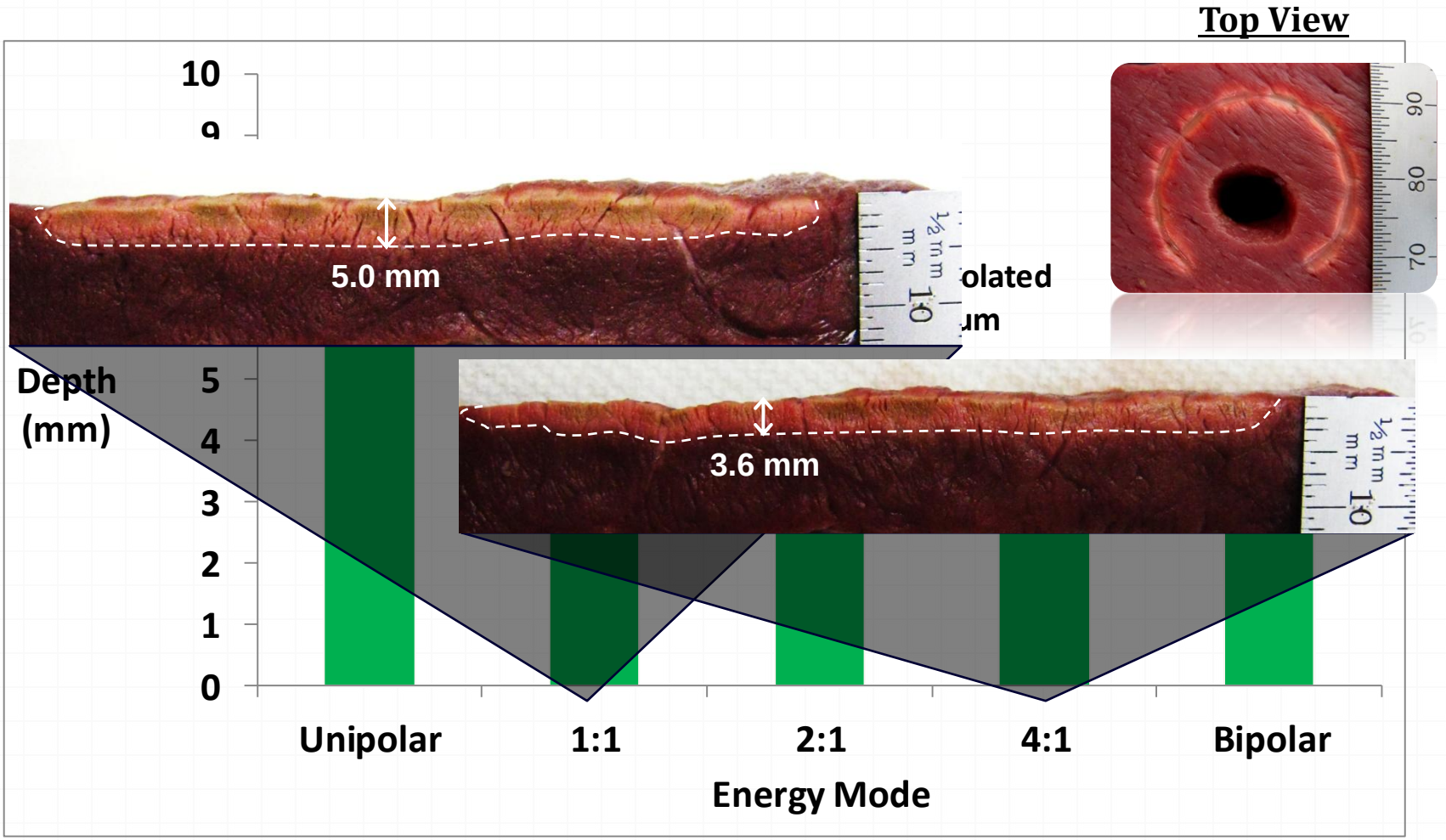
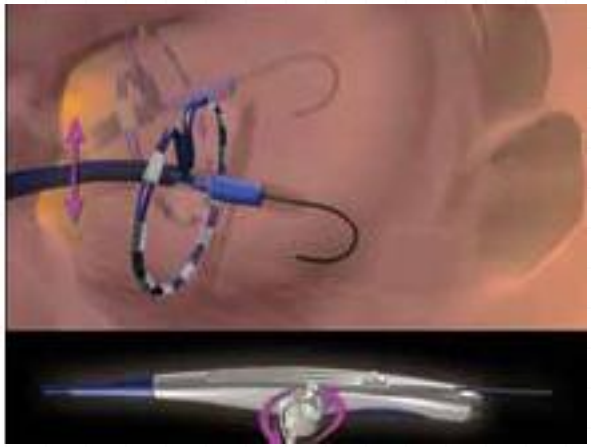
Phased RF Ablation : Lesion Depth Control



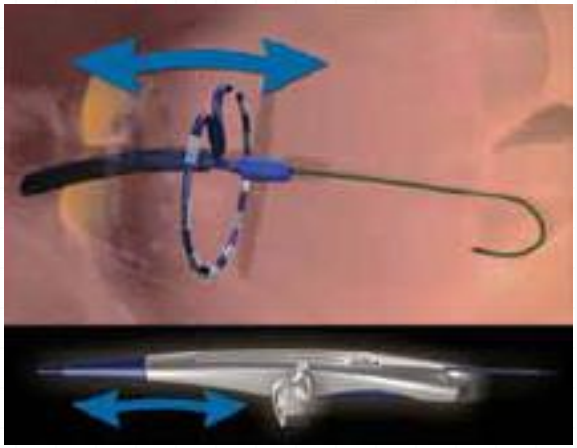
Wijffels MC et al. J Cardiovasc Electrophysiol. 2009;20:1142-8.

PVAC Maneuvers to Improve Tissue Contact

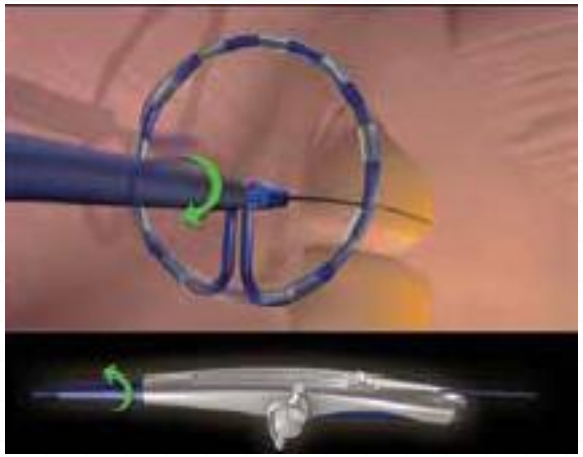
Steering



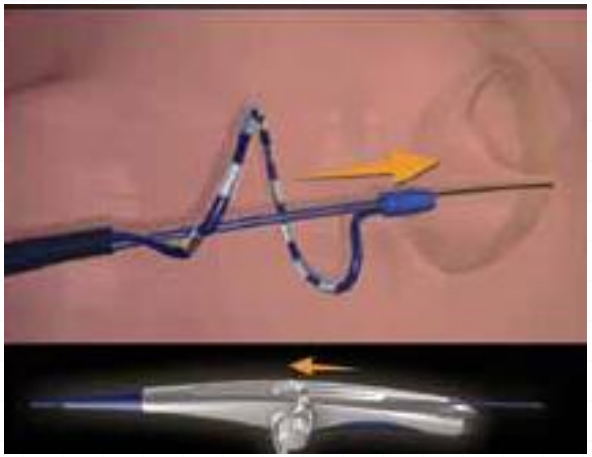
Pulling or Pushing



Rotating

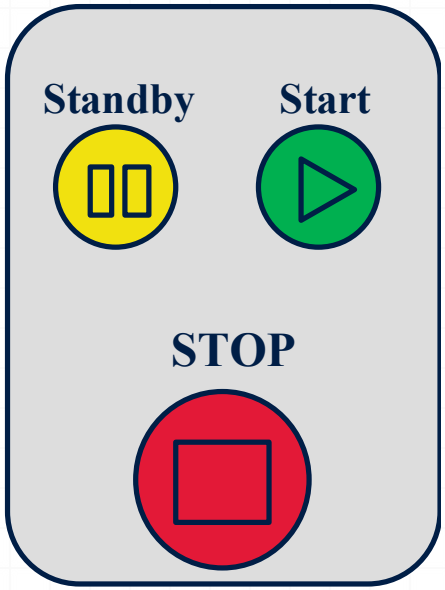


Sliding



Standby, Start, and Stop Buttons

- **Standby button**
  - Pressing **Standby** after catheter positioning and prior to initiating ablation will display electrode temperature information for selected channels
  - Resets Cumulative RF usage display (Press and hold the Standby button for 3 seconds)
- **Start button**
  - Begins energy delivery
  - During ablation an audible tone is emitted and beeps to signal end of ablation
- **STOP button**
  - Can be pressed anytime during ablation to stop energy delivery
  - End of ablation audible tone sounds and generator enters Setup mode



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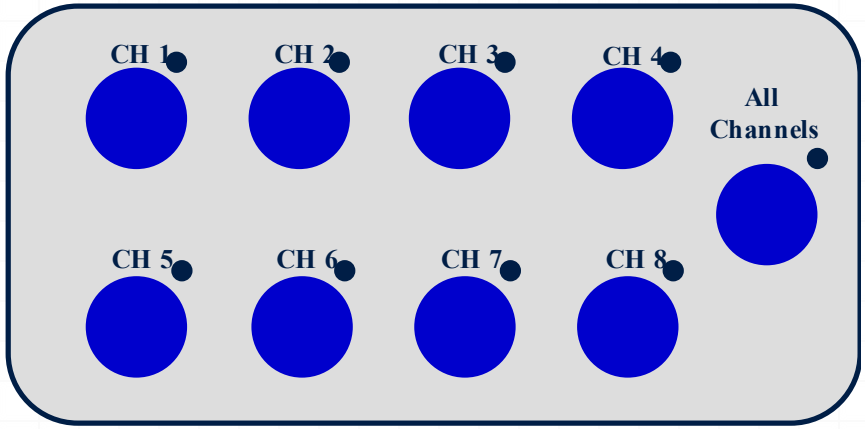
Channel Management

- **Channel buttons** are available in Setup mode when a catheter is connected
- Used to select or de-select ablation channels
  - A green light appears when a channel is selected
- **All Channels** selects or de-selects all channels with a single press
- Channels can also be de-selected during ablation



- PVAC: CH1 – CH5
- MASC: CH1 – CH6
- MAAC: CH1 – CH4

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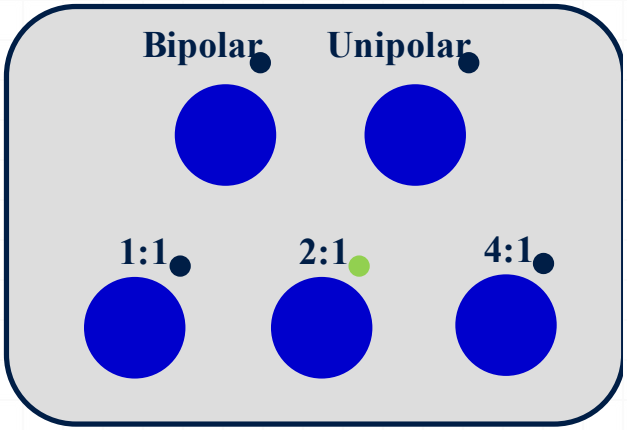
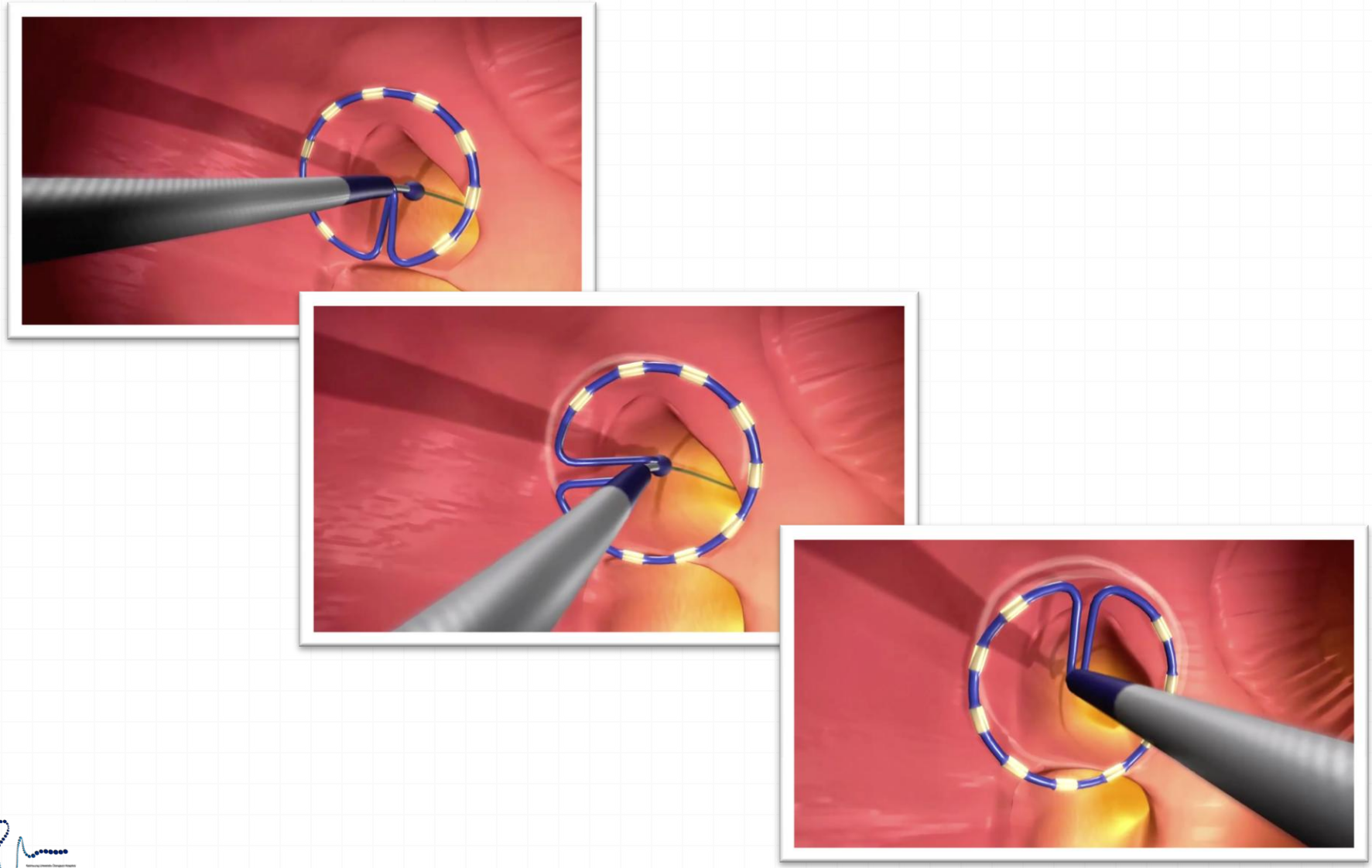
Energy Mode Buttons

- Energy modes: Bipolar, Unipolar, 1:1, 2:1 and 4:1
- The first number refers to bipolar component and second number refers to unipolar component
- Indicator is illuminated for selected energy mode (2:1 in the example)
- The default mode for PVAC is 4:1
- The default mode for MAAC and MASC is 1:1



PVAC Energy Deployment

PVAC Ablation



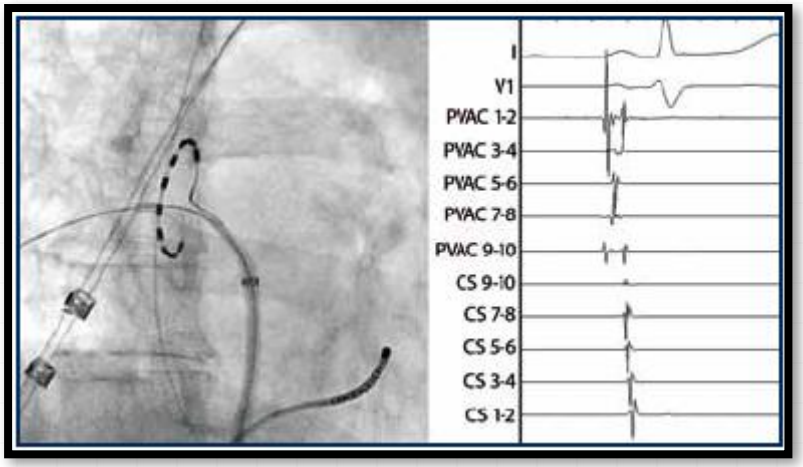
Validation of Pulmonary Vein Isolation

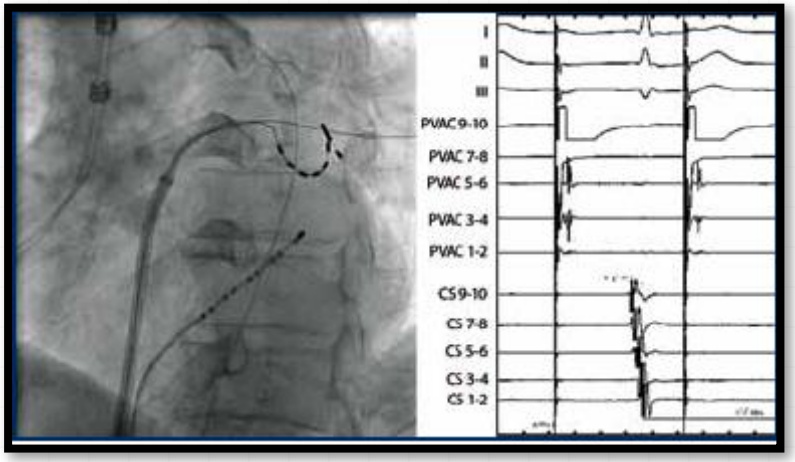
Entrance Block

- Place PVAC distal to the presumed ablation line
- Check for entrance block by mapping during sinus rhythm
  - Distal CS pacing for Left PV's
  - Proximal CS or High Right Atrial pacing for Right PV's

Exit Block

- Place PVAC array within the targeted vein
- Pace at high output from each of the PVAC pairs checking for effect on PV and atrial activations





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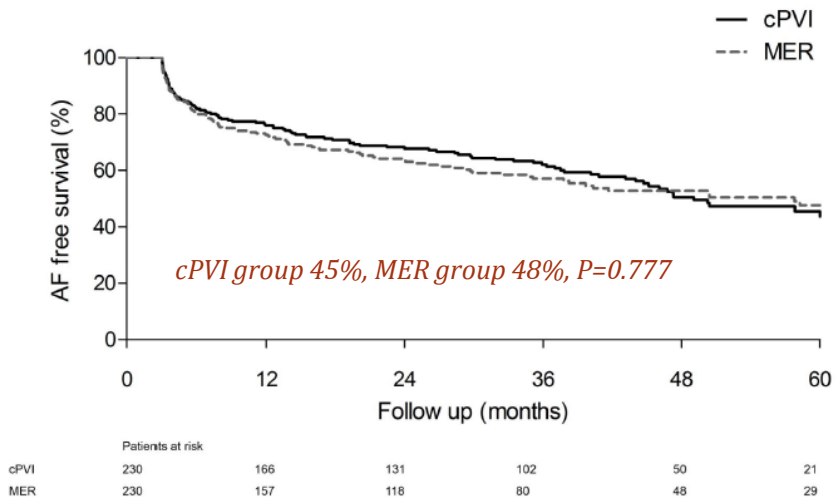
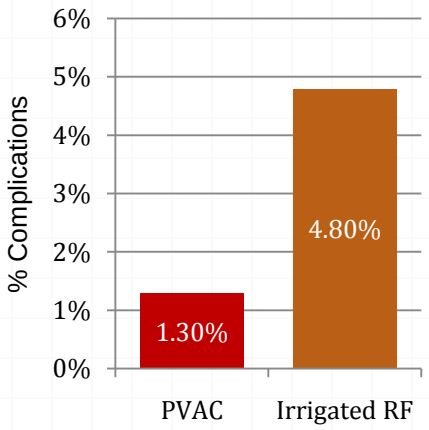
5 Year FU with PVAC vs. Irrigated RF

Procedure Success off Drugs



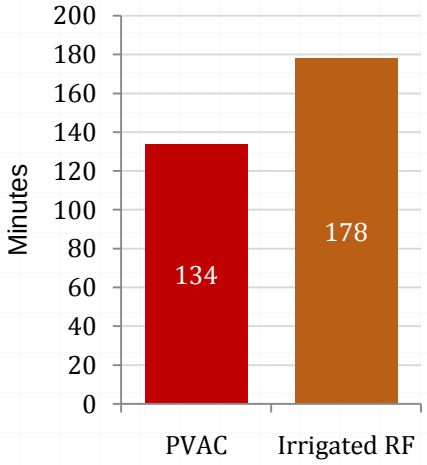
- cPVI = PVI with Conventional RF using iRF
- MER = Multi-Electrode Radiofrequency using Phased RF

Major Complication Rate at 60 months



*Statistically significant

Procedure Time



*Statistically significant

- PVAC
- Irrigated RF

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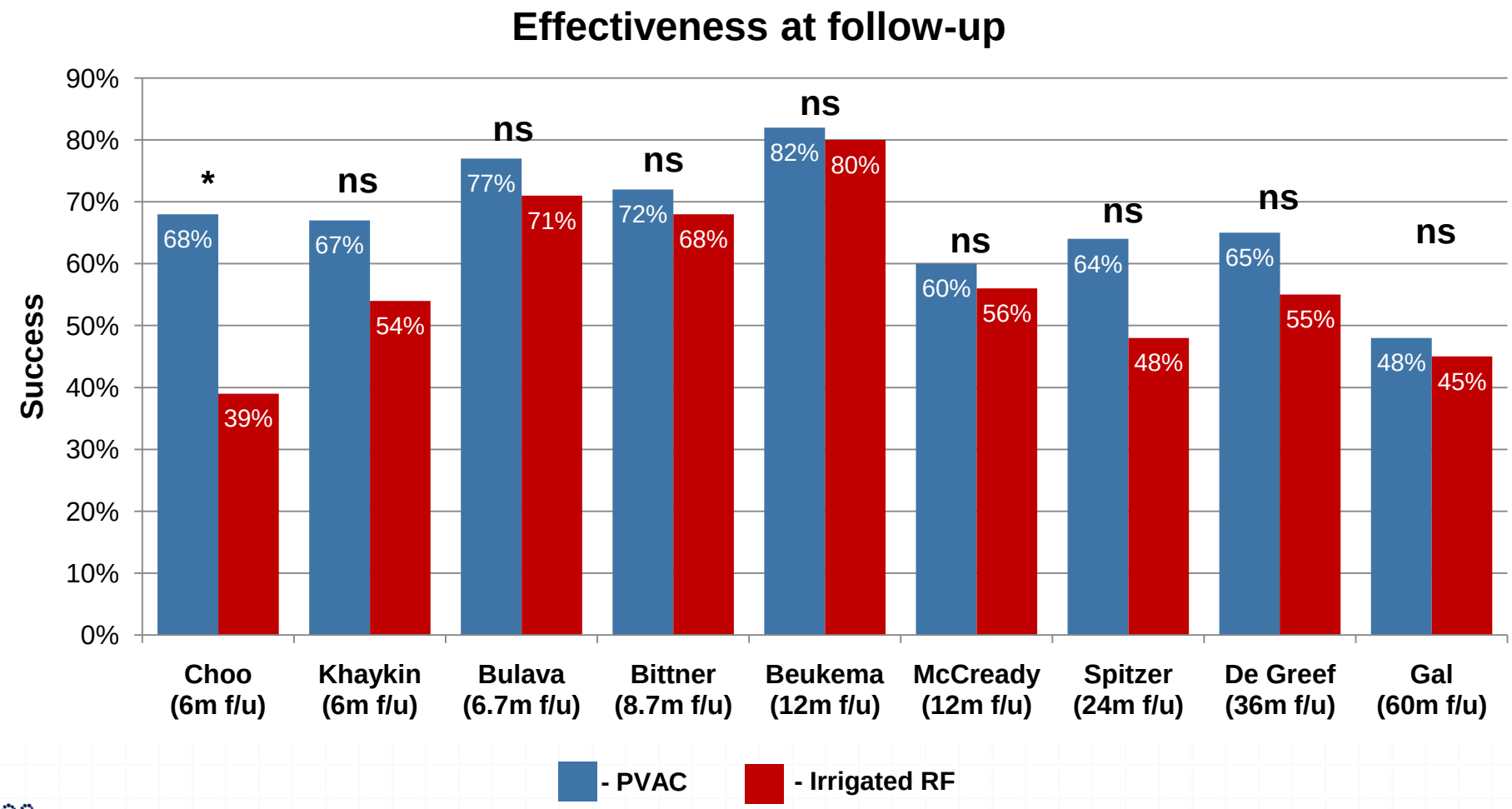
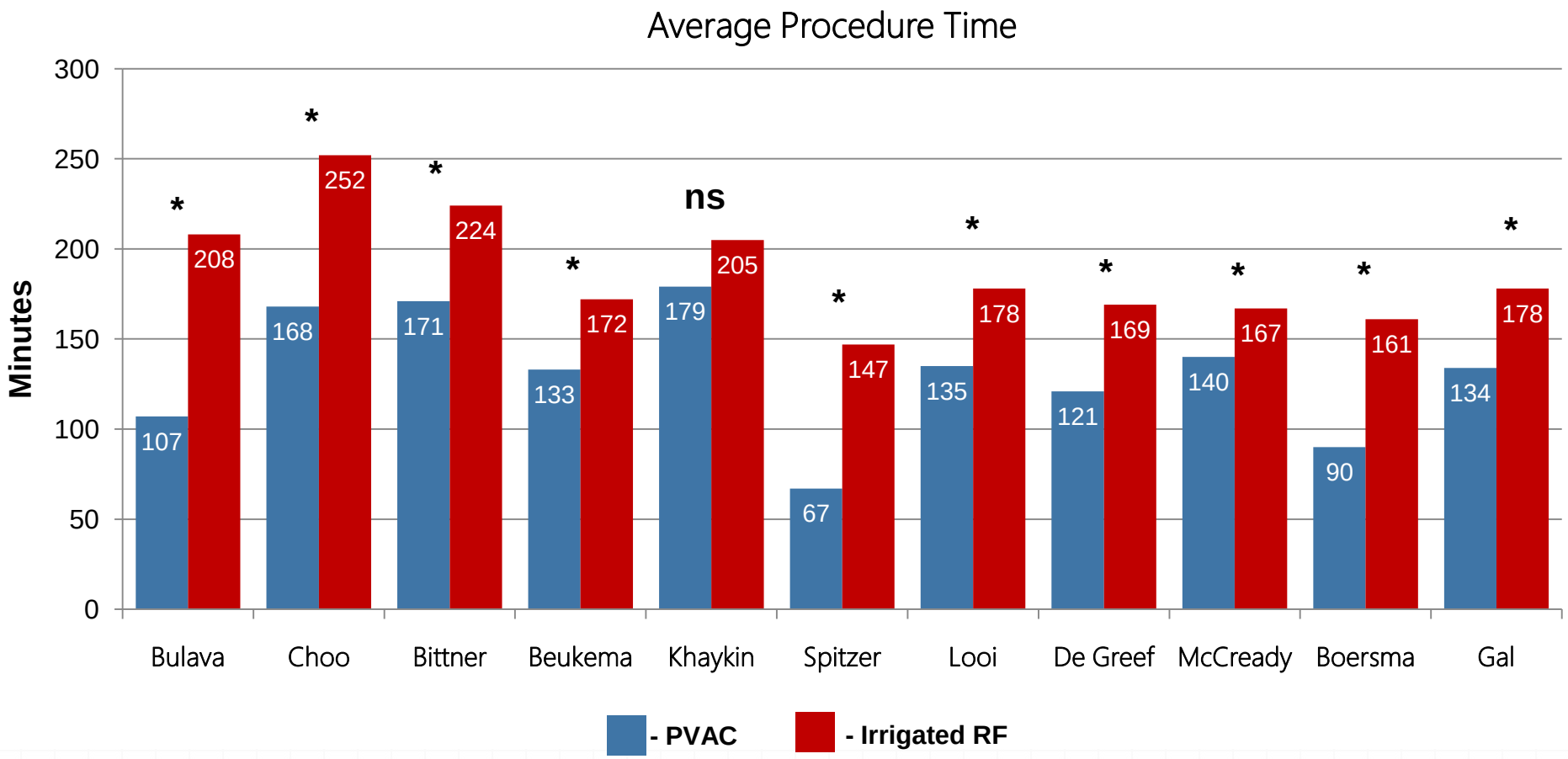
Gal P et al. Int J Cardiol. 2014;176:891-5.

Effectiveness : PVAC vs. Irrigated RF



*Statistically significant

Procedure Time : PVAC vs. Irrigated RF



*Statistically significant

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Procedure Data : WACA vs. PVAC

Table 2 Procedural data

	WACA mean (range)	PVAC mean (range)	*P* value
Mean procedure time (min)	167 ± 42 (95–270)	140 ± 43 (70–270)	<0.0001
Left atrial dwell time (min)	133 ± 36 (90–210)	111 ± 35 (55–220)	<0.0001
Fluoroscopy time (min)	42 ± 20 (9–86)	35 ± 16 (4–86)	<0.05
RF application time (min)	40 ± 14 (8–49)	27 ± 8 (13–68)	<0.0001
Mean number of RF applications per vein			
PVAC			
L. superior PV	–	8	–
L. inferior PV	–	9	–
Left common PV	–	15	–
R. superior PV	–	7	–
R. inferior PV	–	6	–
R. common PV	–	10	–

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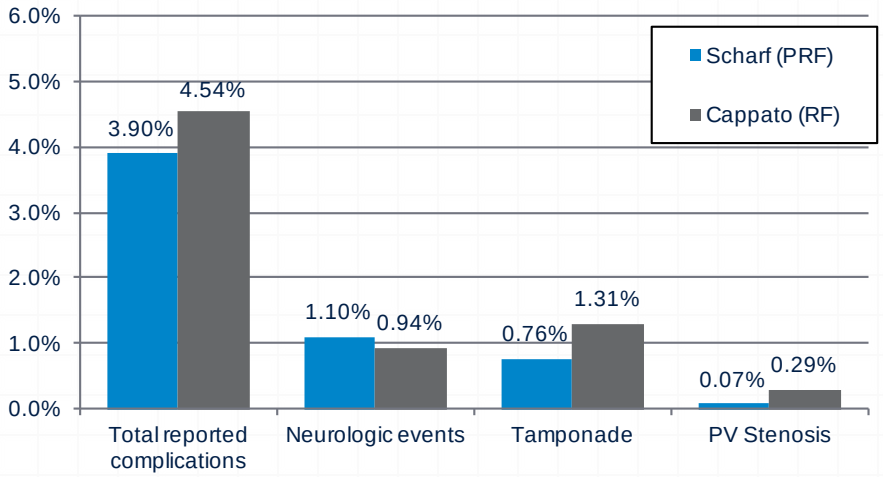
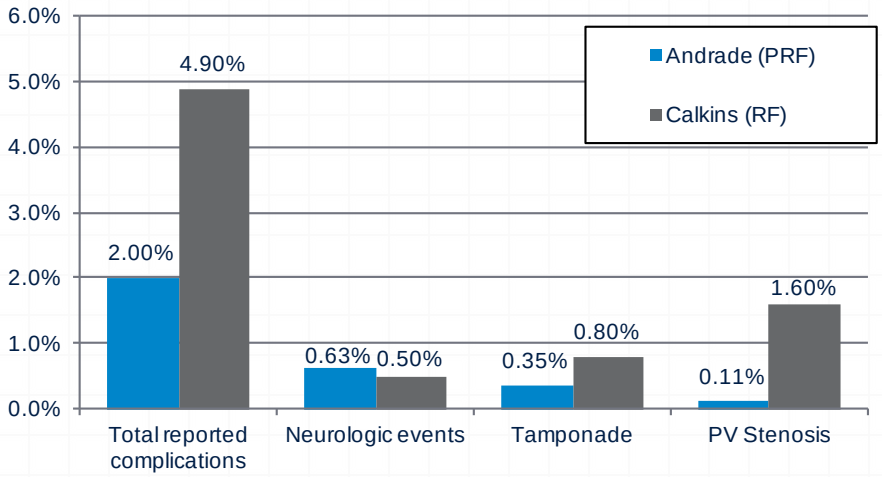
McCready J et al. Europace. 2014 Aug;16(8):1145-53

Safety : PVAC vs. Irrigated RF

Scharf Survey Results



Andrade Meta-Analysis Results



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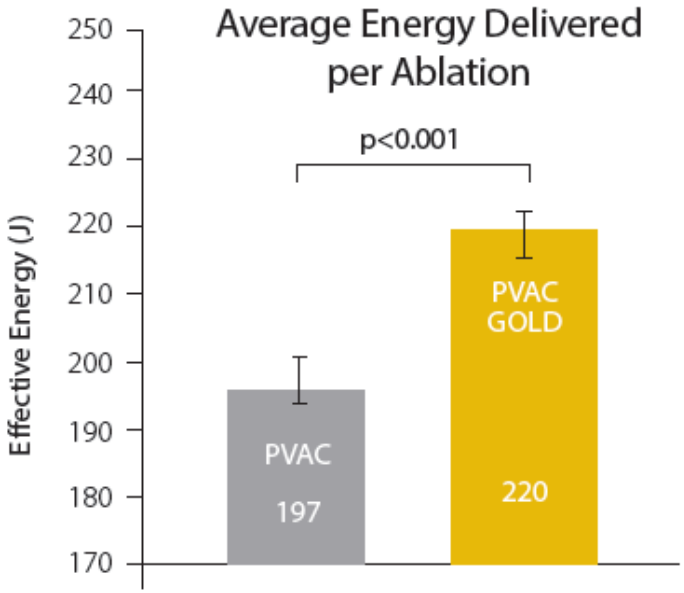
PVAC Gold vs. PVAC

	PVAC GOLD	ERACE	p Value
Procedure time	104 ± 31 min	100 ± 35 min	p=0.5375
LA dwell time	60 ± 18 min	64 ± 27 min	p=0.3007
Fluoroscopy time	16 ± 7 min	-	-
RF applications	20 ± 10	29 ± 16	p=0.0010



1. De Greef Y, et al. Phased RF Evaluation of Acute Pulmonary Vein Isolation in Paroxysmal AF With New GENius and PVAC GOLD: the PRECISION-GOLD Study. Circulation. 2014;130:Suppl 2 A18975.
2. Verma A, Debruyne P, Nardi S, et al. Evaluation and reduction of asymptomatic cerebral embolism in ablation of AF, but high prevalence of chronic silent infarction: Results of the ERACE trial. Circ Arrhythm Electrophysiol. 2013 Oct;6(5):835-842.

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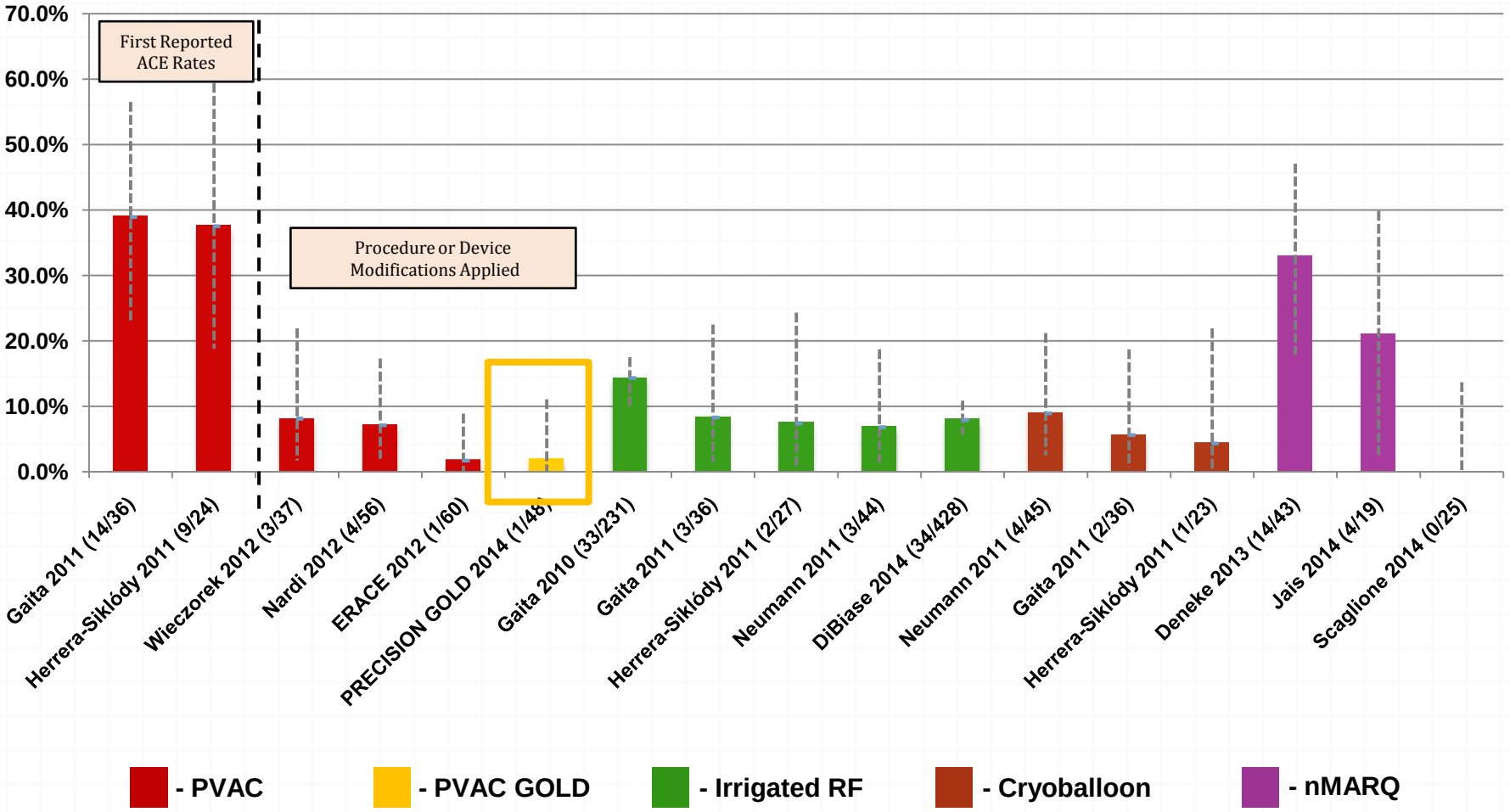
PVAC GOLD ACE Rate : 2.1%

Amongst the Lowest of any Technology



Caution: Clinical results across studies/protocols may not be comparable.
All studies included used 1.5T MRI scanner and used a consistent lesion definition as per Gaita/Herrera-Siklódy (DWI + ADC + FLAIR)

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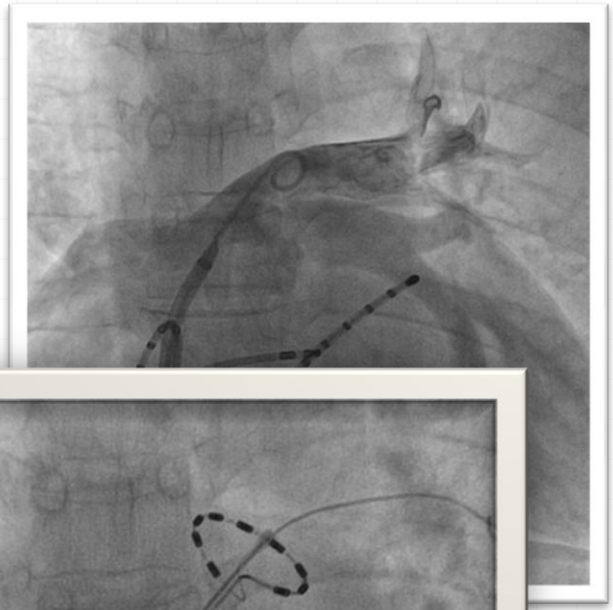
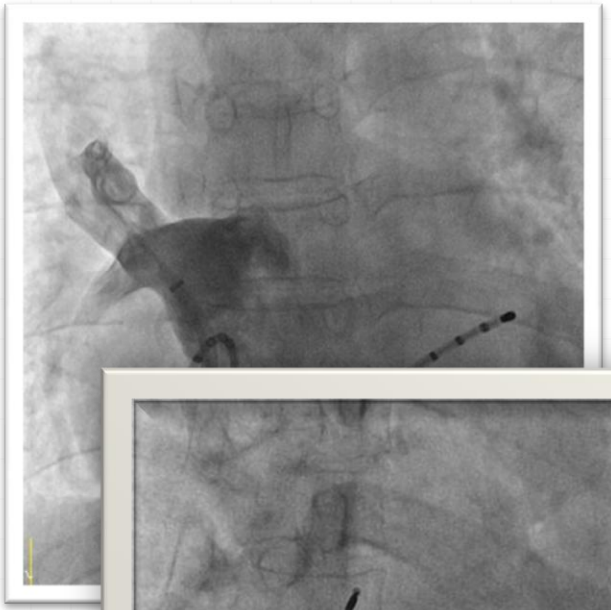
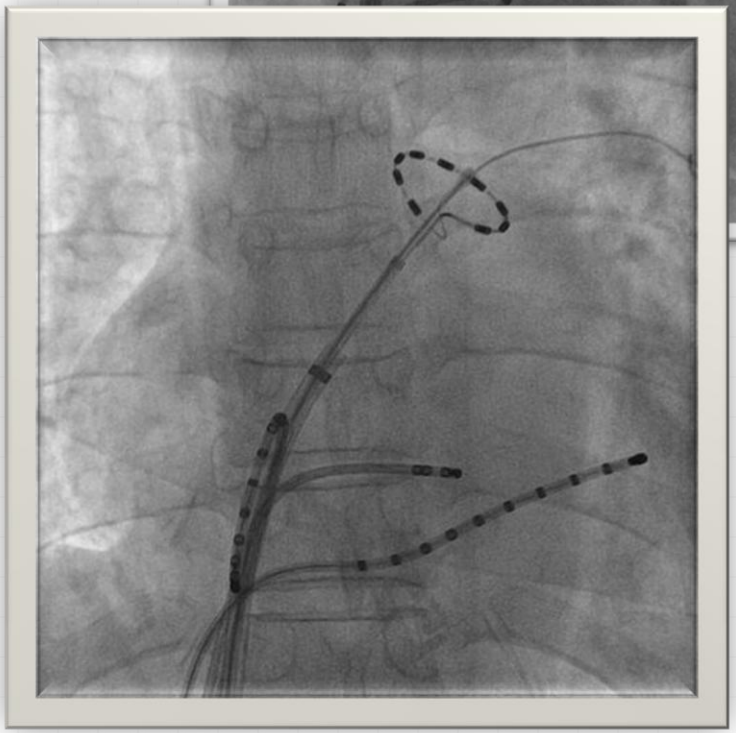
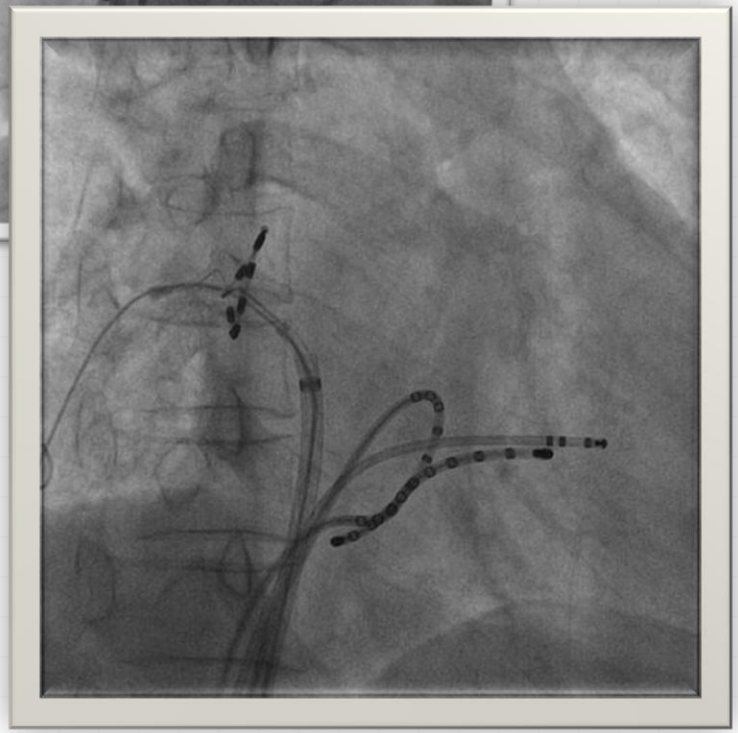
De Greef Y et al. Europace. 2016

Case 1. 59 Y.O. Female, Paroxysmal AF

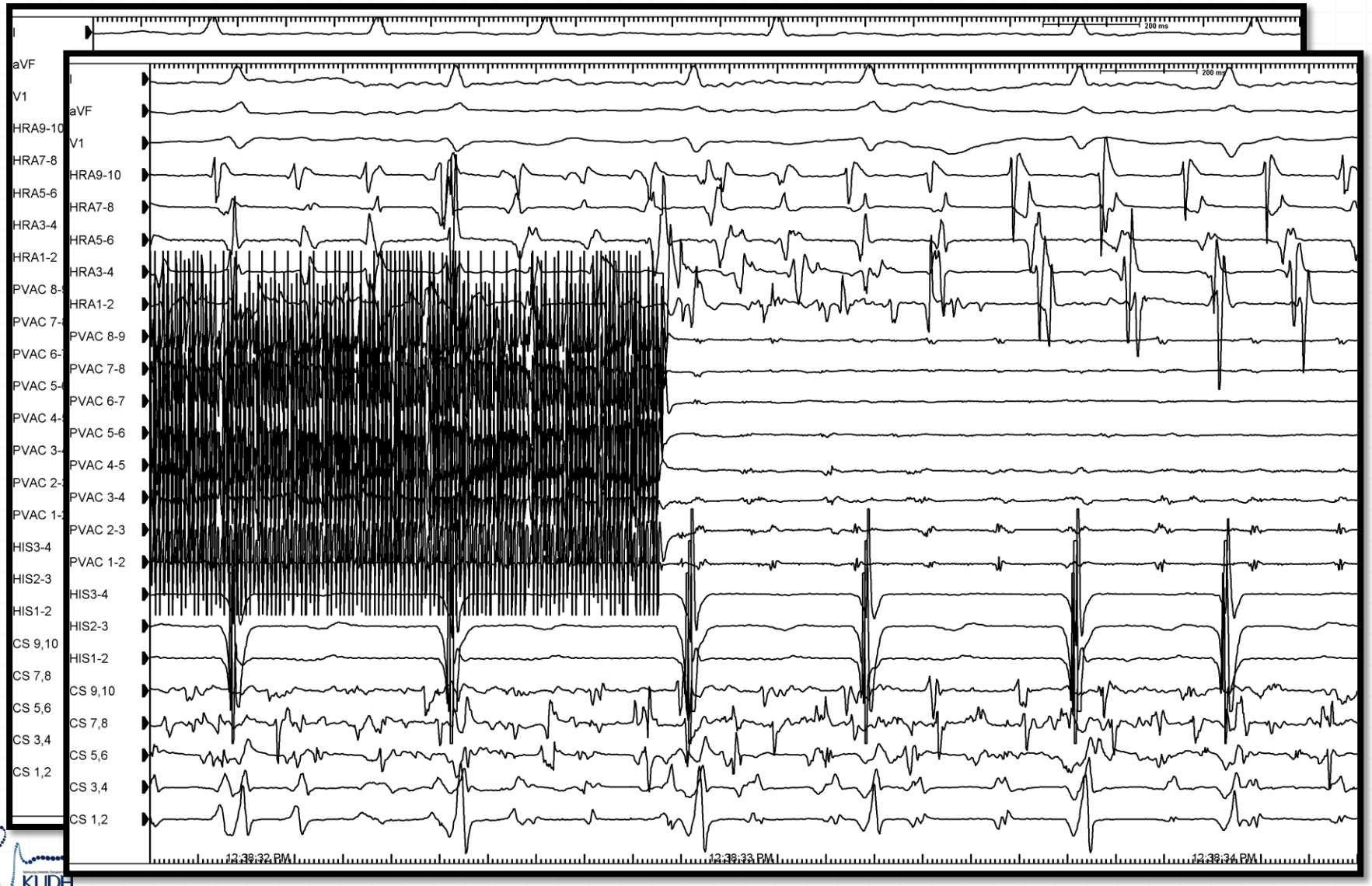




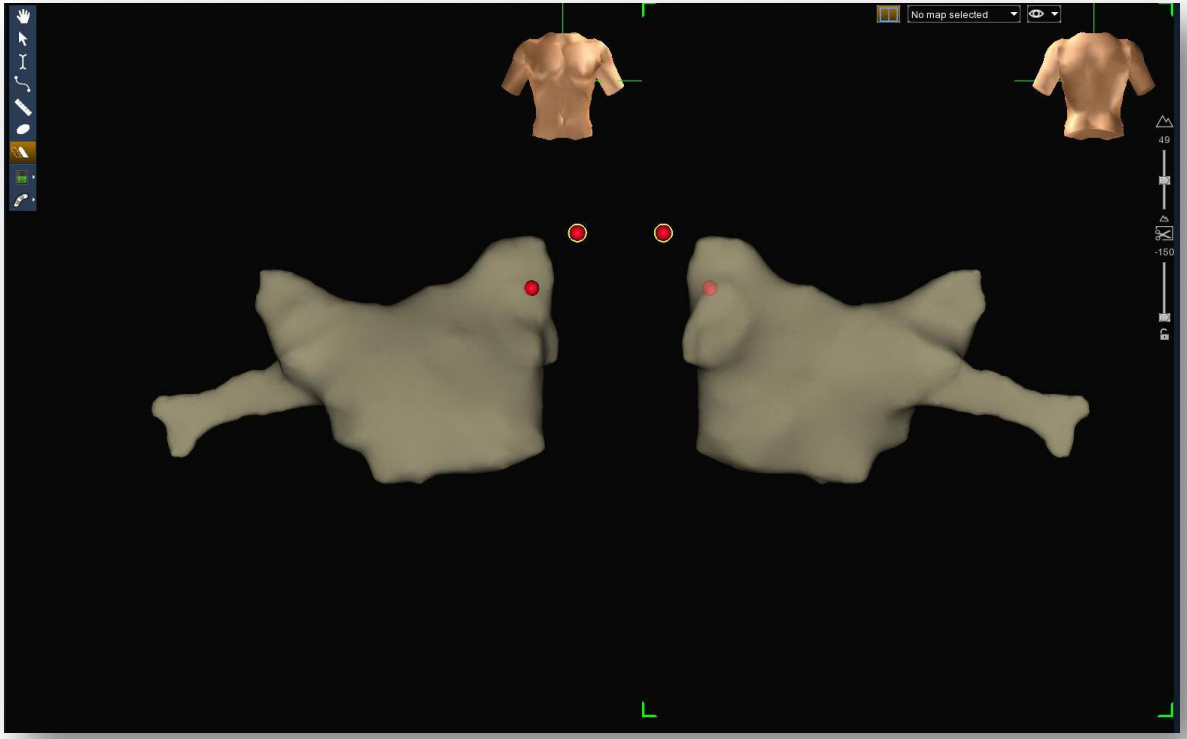




LSPV Ablation

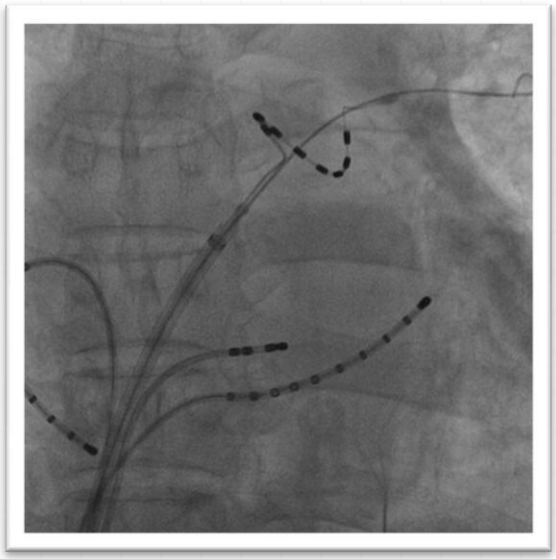


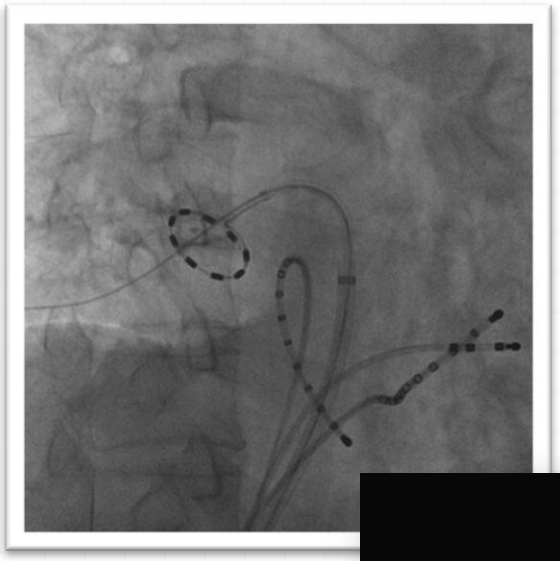
Additional Ablation for PVI

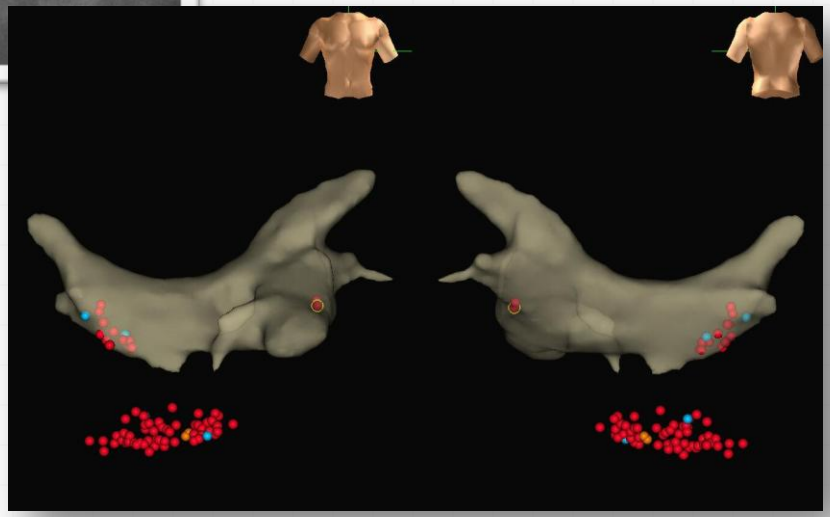


Total Procedure time: 125min
Fluoroscopic Time : 20min 51sec

Case 2. 60 Y.O. Male, Paroxysmal AF

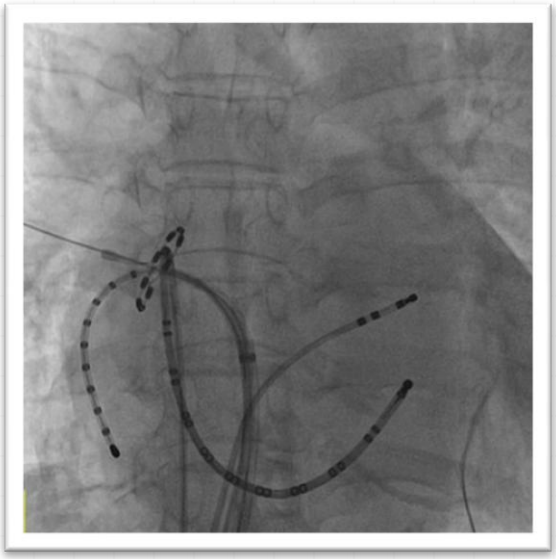


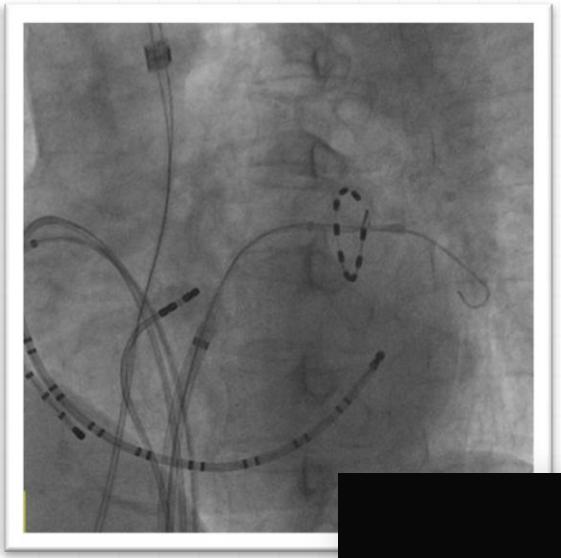




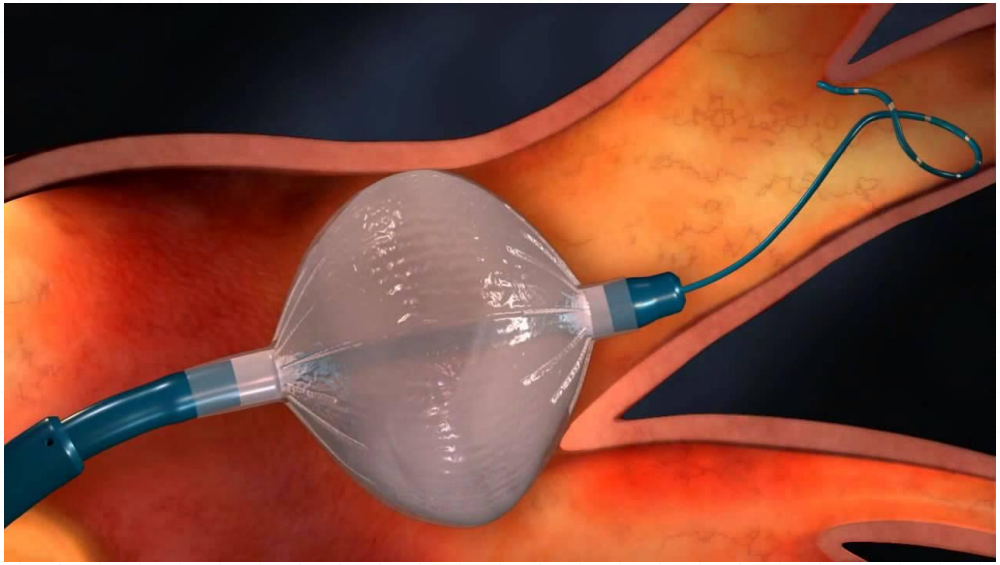
Total Procedure time: 155min
Fluoroscopic Time : 40min 19sec

Case 3. 72 Y.O. Female, Persistent AF





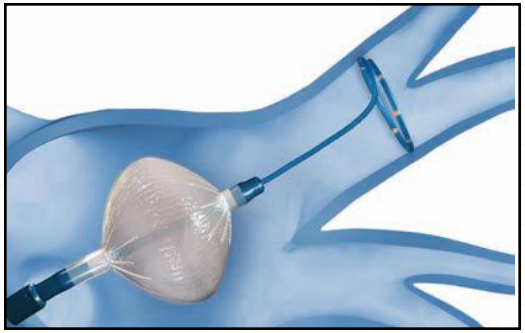
Total Procedure time: 125min
Fluoroscopic Time : 32min 53sec



Cryoballoon Ablation

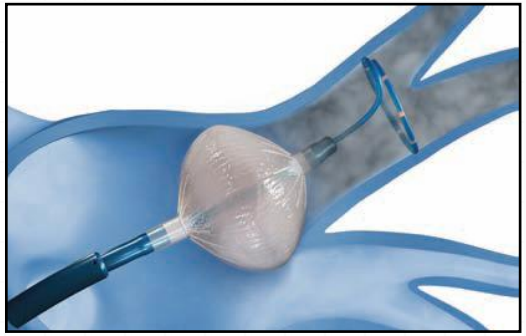
Cryoballoon Ablation

1. Access targeted vein



2. Inflate and position

3. Occlude and ablate



4. Assess PVI

Cryoballoon vs. RFCA : FIRE AND ICE Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation

Karl-Heinz Kuck, M.D., Josep Brugada, M.D., Alexander Fürnkranz, M.D., Andreas Metzner, M.D., Feifan Ouyang, M.D., K.R. Julian Chun, M.D., Arif Elvan, M.D., Ph.D, Thomas Arentz, M.D., Kurt Bestehorn, M.D., Stuart J. Pocock, Ph.D., Jean-Paul Albenque, M.D., Ph.D., and Claudio Tondo, M.D., Ph.D., for the FIRE AND ICE Investigators*

ABSTRACT

BACKGROUND

Current guidelines recommend pulmonary-vein isolation by means of catheter ablation as treatment for drug-refractory paroxysmal atrial fibrillation. Radiofrequency ablation is the most common method, and cryoballoon ablation is the second most frequently used technology.

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Kuck KH et al. N Engl J Med. 2016 Apr

Cryoballoon vs. RFCA : FIRE AND ICE Trial

Table 2. Efficacy End Points.*

End Point	Radiofrequency Group (N=376)	Cryoballoon Group (N=374)	Hazard Ratio (95% CI)†	P Value
Primary efficacy end point — no. of patients (%)‡	143 (35.9)§	138 (34.6)§	0.96 (0.76–1.22)	<0.001¶
Components of the primary efficacy end point — no. of patients				
Recurrent atrial arrhythmia	87	80	—	—
Antiarrhythmic drug treatment	49	51	—	—
Repeat ablation	7	7	—	—
Secondary efficacy end points				
Death from any cause — no. of patients	0	2‖	—	0.25**
Death from arrhythmia — no. of patients	0	0	—	—
Total procedure duration — min	140.9±54.9	124.4±39.0	—	<0.001††
Left atrial dwell time — min‡‡	108.6±44.9	92.3±31.4	—	<0.001††
Total fluoroscopy time — min§§	16.6±17.8	21.7±13.9	—	<0.001††
Rehospitalization for cardiovascular causes — no. of patients (%)	55 (13.5)§	44 (9.4)§	0.78 (0.53–1.16)	0.28**

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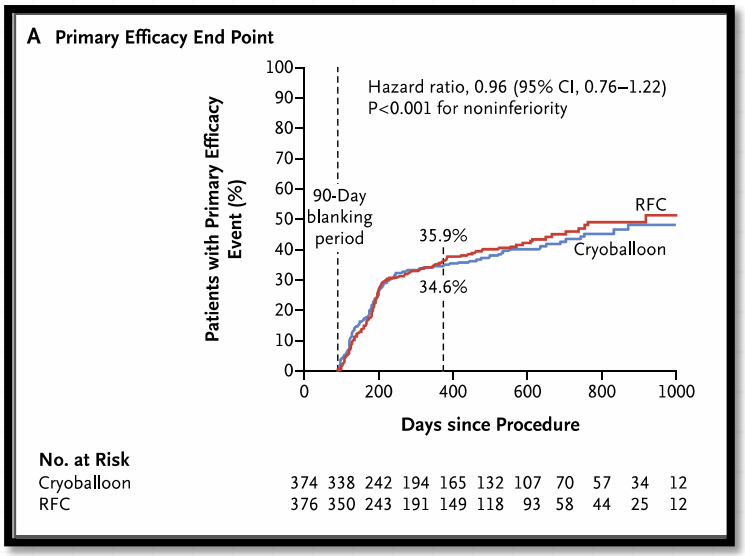
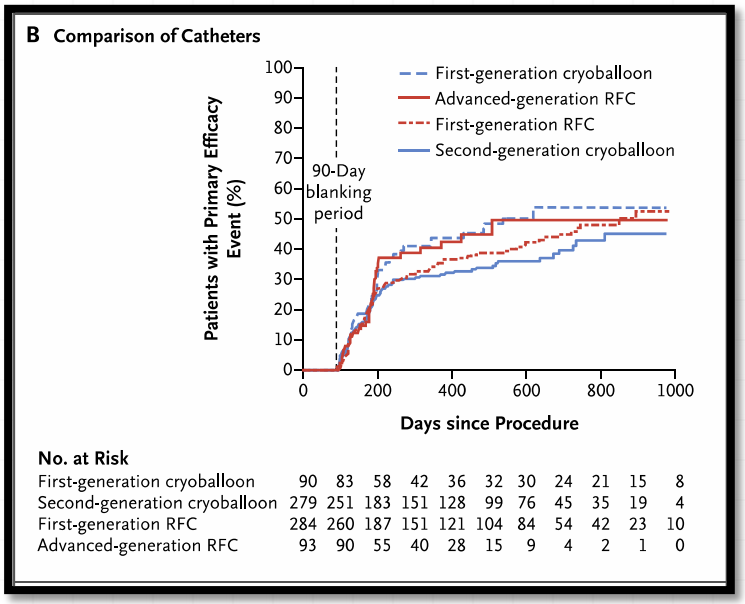
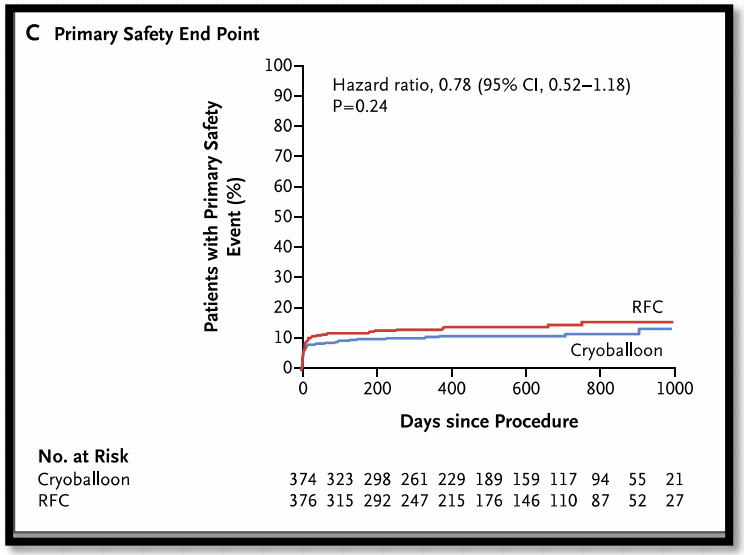
Cryoballoon vs. RFCA : FIRE AND ICE Trial







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Cryoballoon vs. RFCA : FIRE AND ICE Trial

Table 3. Safety End Points.

End Point	Radiofrequency Group (N=376)	Cryoballoon Group (N=374)	P Value*
	no. of patients (%)		
Primary safety end point†	51 (12.8)‡	40 (10.2)‡	
Death from any cause§	0	2 (0.5)¶	0.50
Stroke or TIA from any cause§	2 (0.5)	2 (0.5)	1.00
Atrial arrhythmia§‖	13 (3.5)	8 (2.1)	0.38
★Atrial flutter or atrial tachycardia	10 (2.7)	3 (0.8)	0.09
Non–arrhythmia-related serious adverse events§	36 (9.6)	28 (7.5)	0.36
★Groin-site complication**	16 (4.3)	7 (1.9)	0.09
★Unresolved phrenic nerve injury††			
At discharge	0	10 (2.7)	0.001
At 3 months	0	2 (0.5)	0.25
At >12 months	0	1 (0.3)	0.50
Cardiac tamponade or pericardial effusion	5 (1.3)	1 (0.3)	0.22
Pulmonary or bronchial complication	4 (1.1)	2 (0.5)	0.69
Transient neurologic complication	3 (0.8)	1 (0.3)	0.62
Dyspnea	2 (0.5)	1 (0.3)	1.00
Gastrointestinal complication	2 (0.5)	1 (0.3)	1.00
Other, nonarrhythmia cardiac complications‡‡	0	3 (0.8)	0.12
Anxiety	0	1 (0.3)	0.50
Contrast media reaction	1 (0.3)	0	1.00
Contusion	1 (0.3)	0	1.00
Esophageal ulcer	0	1 (0.3)	0.50
Hematuria	1 (0.3)	0	1.00
Local edema	1 (0.3)	0	1.00
Atrioesophageal fistula	0	0	—
Pulmonary vein stenosis	0	0	—

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Summary

- AF ablation with optimal CF demonstrated improved clinical outcome.
- Multi-electrode phased RF ablation was superior in procedure duration and ablation time, with less complications.
- Pulmonary vein isolation by means of cryoballoon ablation was noninferior to pulmonary vein isolation by radiofrequency ablation in terms of efficacy and safety.

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Thanks for your attention !!

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