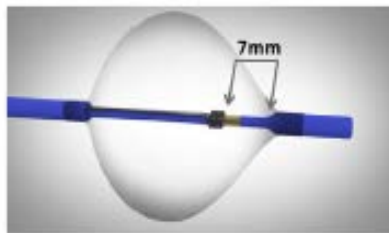


Second generation cryoballoon ablation: clinical experience and perspectives

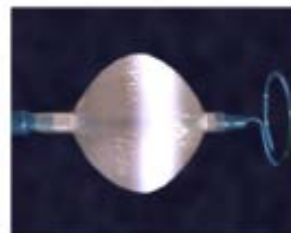
*Gian Battista Chierchia MD, PhD
HRMC, VUB-UZ Brussel, Brussels
Belgium*

Acute Outcomes

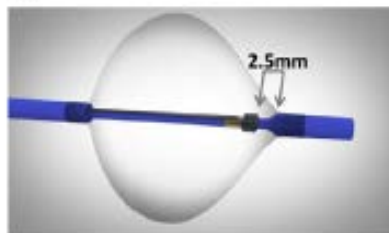
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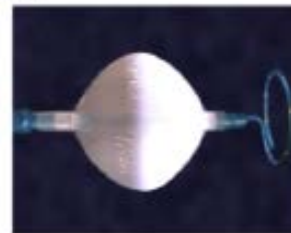
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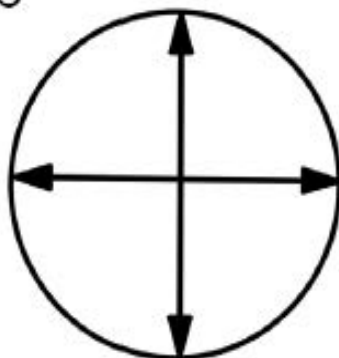
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B'

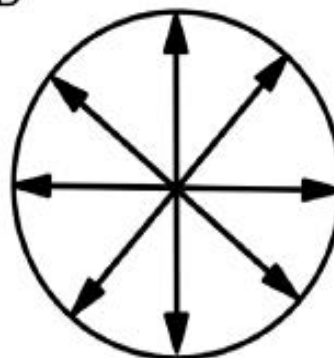


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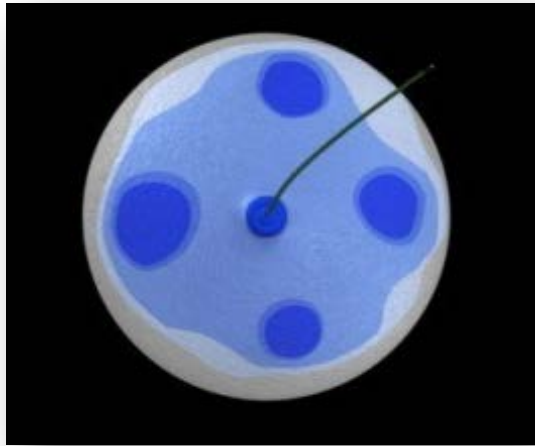
Artic Front

D

Artic Front
Advance

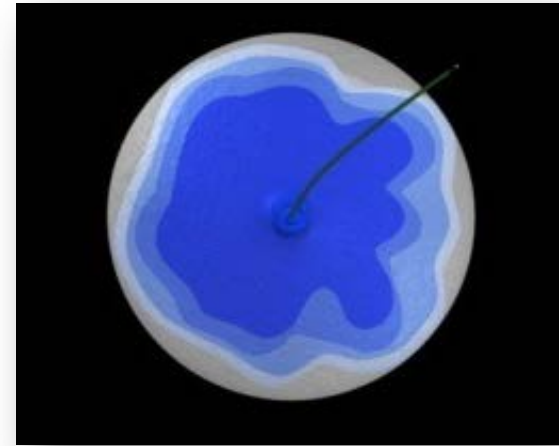
Improved Temperature Uniformity with Arctic Front Advance Cryoballoon

Arctic Front™

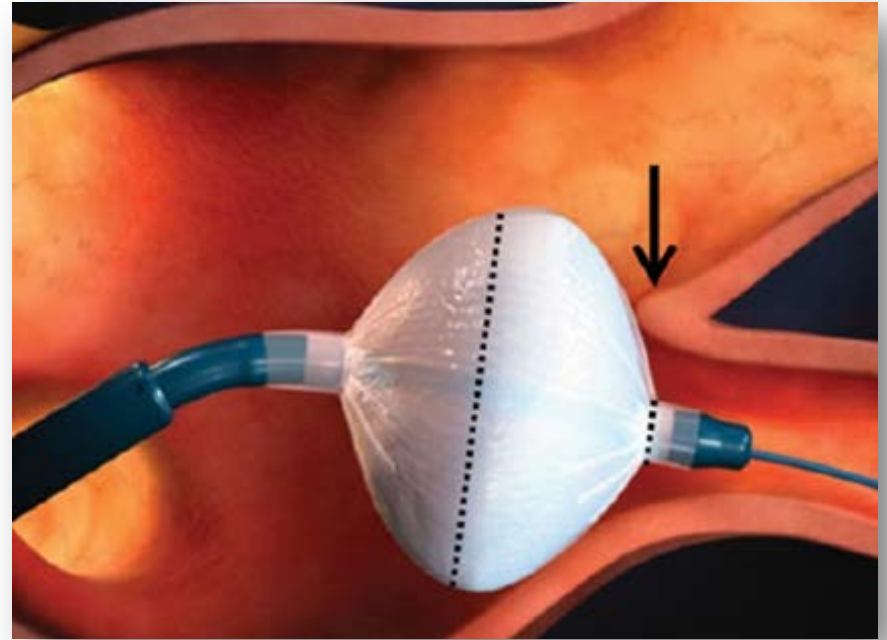
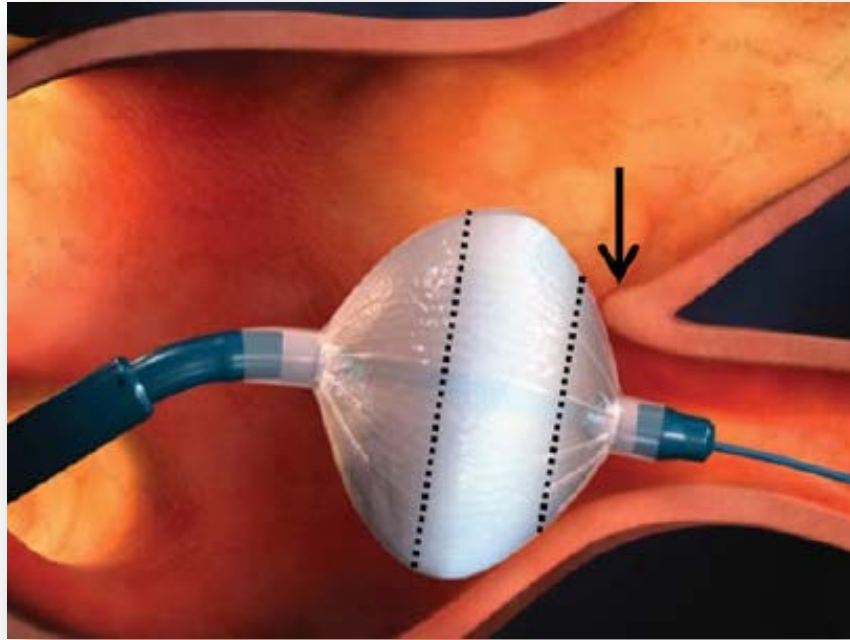


Refrigerant distribution near equator of balloon with four jets.

Arctic Front Advance™



Improved surface temperature gradient



Pulmonary Vein Isolation Using a Second-Generation Cryoballoon Catheter: A Randomized Comparison of Ablation Duration and Method of Deflation

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LÉNA RIVARD, M.D.,* LAURENT MACLE, M.D.,* BERNARD THIBAUT, M.D.,*
MARIO TALAJIC, M.D.,* DENIS ROY, M.D.,* and PAUL KHAIRY, M.D., Ph.D.,‡

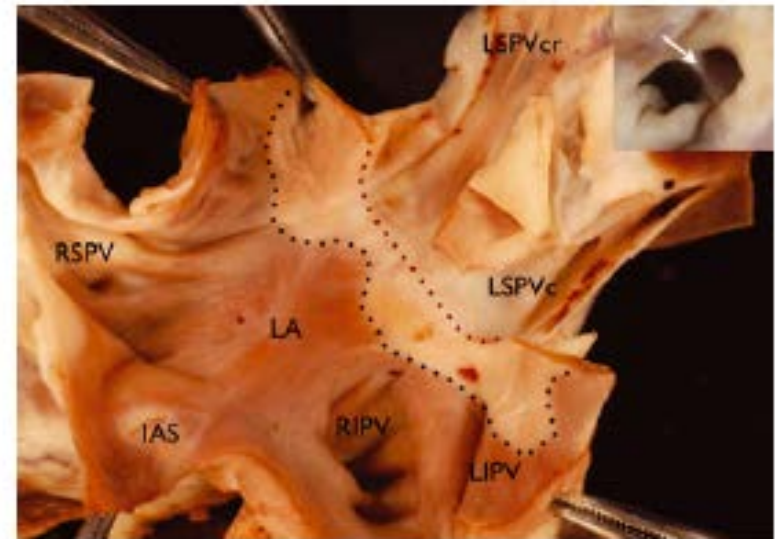
From the *Electrophysiology Service, Department of Cardiology, Montreal Heart Institute, Université de Montréal, Montreal, Canada; †Medtronic CryoCath, Pointe-Claire, QC, Canada; and ‡Montreal Heart Institute Coordinating Center, Montreal, Canada

TABLE 2

Procedural and Ablation Lesion Characteristics for Left-Sided Pulmonary Veins Randomized to 2- versus 4-Minute Cryoapplications

	2 Minutes N = 29	4 Minutes N = 30	P- Value
Temperature at 30 seconds, °C	-32.8 ± 8.6	-33.4 ± 5.9	0.6872
Nadir ablation temperature, °C	-46.6 ± 6.5	-49.3 ± 8.2	0.1762
Time from end ablation to 0°C, seconds	5 ± 2	5 ± 2	0.9245
Time from end ablation to +20°C, seconds	19 ± 9	23 ± 14	0.5229
Acute PVI with single cryoablation, N (%)	26 (89.7)	27 (90.0)	0.9654
Real-time PV potential monitoring, N (%)	18 (62.1)	16 (53.3)	0.6801
Time to PVI, seconds	31 ± 16	28 ± 15	0.3107
Temperature at PVI, °C	-28.4 ± 14.3	-28.4 ± 15.2	0.8686
Circumferential transmural lesions, N (%)	25 (86.2)	21 (70.0)	0.1366
Maximum lesion depth, µm	2310 ± 641	2528 ± 1006	0.3880
Mean lesion depth, µm	1061 ± 702	2007 ± 915	0.6481
Maximum neointimal thickness, µm	191 ± 231	320 ± 3019	0.0177
Mean neointimal thickness, µm	136 ± 184	224 ± 208	0.0071

LSPV, left superior pulmonary vein; LIPV, left inferior pulmonary vein; PV, pulmonary vein; PVI, PV isolation.



Improved *In Vivo* Performance of Second-Generation Cryoballoon for Pulmonary Vein Isolation

NICOLAS COULOMBE, M.A.Sc.,* JAIME PAULIN, D.V.M., D.A.C.V.P.,† and WILBER SU, M.D.‡

From the *Medtronic CryoCath LP, Pointe-Claire, Canada; †Medtronic Physiological Research Laboratories, Minneapolis, USA; and ‡Heart Rhythm Specialists, Phoenix, Arizona, USA

TABLE 2
Histopathological Data of Pulmonary Vein Tissue

	AF23	AFA23	P-Value	AF28	AFA28	P-Value
Circumferentially transmural lesion	3/5	5/5	-	3/5	5/5	-
Maximal lesion depth (μm)*	3016 $\pm$ 1134	2988 $\pm$ 1126	0.92	3696 $\pm$ 1136	3352 $\pm$ 1056	0.92
Maximal neointimal thickness (μm)	277 $\pm$ 191	158 $\pm$ 74	0.39	137 $\pm$ 55	134 $\pm$ 127	0.97
Minimal neointimal thickness (μm)	53 $\pm$ 92	43 $\pm$ 36	0.75	40 $\pm$ 10	29 $\pm$ 41	0.68
Average neointimal thickness (μm)	165 $\pm$ 140	101 $\pm$ 44	0.46	88 $\pm$ 28	82 $\pm$ 81	0.9

Improved Procedural Efficacy of Pulmonary Vein Isolation Using the Novel Second-Generation Cryoballoon

ALEXANDER FURNKRANZ, M.D.,* STEFANO BORDIGNON, M.D.,* BORIS SCHMIDT, M.D.,*
MELANIE GUNAWARDENE,* BRITTA SCHULTE-HAHN, M.D.,* VERENA URBAN, M.D.,*
FRANK BODE, M.D.,† BERND NOWAK, M.D.,* and JULIAN K. R. CHUN, M.D.*

From the *Cardioangiologisches Centrum Bethanien, Medizinische Klinik III, Markus Krankenhaus, Frankfurt am Main; and
†Universitätsklinikum Medizinische Klinik II, Lübeck, Germany

TABLE 2
Procedural Parameters

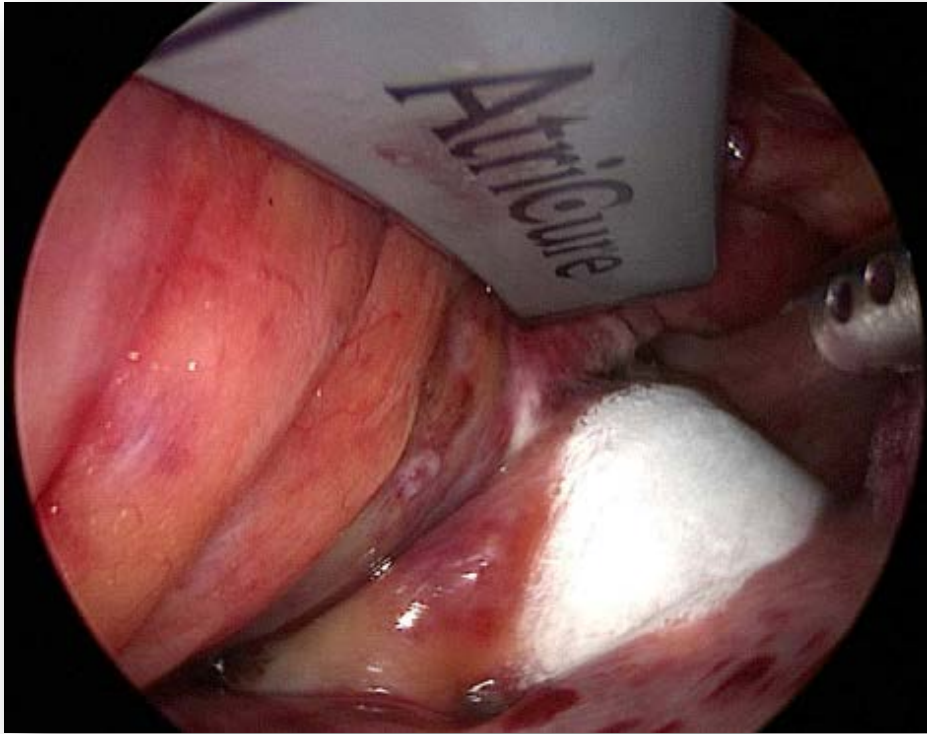
	CB-1G	CB-2G	P Value
Balloon applications per vein (excluding bonus)	1.8 ± 1.2	1,3 ± 0,8	<0.001
Distance to achieve proximal electrode (mm)	18 ± 8	12 ± 5	<0.001
TpVI (seconds)	79 ± 60	52 ± 36	0.049
Procedure duration (minutes)	128 ± 27	98 ± 30	<0.001
Fluoroscopy exposure (minutes)	19.5 ± 7.4	13,4 ± 5,3	0.001
Contrast medium (mL)	134 ± 33	120 ± 34	n.s.

CB-1G = first-generation cryoballoon; CB-2G = second-generation cryoballoon; TpVI = time from start of freezing to pulmonary vein isolation; n.s. = nonsignificant.

TABLE 3
Frequency of Single-Shot PVI and Real-Time PVI Visualization

	Single- Shot PVI		P	Real-Time PVI Visualization		P
	CB-1G	CB-2G		CB-1G	CB-2G	
LSPV	60%	77%	n.s.	57%	81%	0.054
LIPV	60%	100%	<0.001	57%	81%	0.054
LCPV	—	75%	—	—	25%	—
RSPV	37%	80%	0.001	53%	90%	0.002
RIPV	47%	80%	0.007	30%	60%	0.02
Overall	51%	84%	<0.001	49%	76%	<0.001

PVI = pulmonary vein isolation; PV = pulmonary vein; LS = left superior; LI = left inferior; LC = left common; RS = right superior; RI = right inferior; CB-1G = first-generation cryoballoon; CB-2G = second-generation cryoballoon; n.s. = nonsignificant.

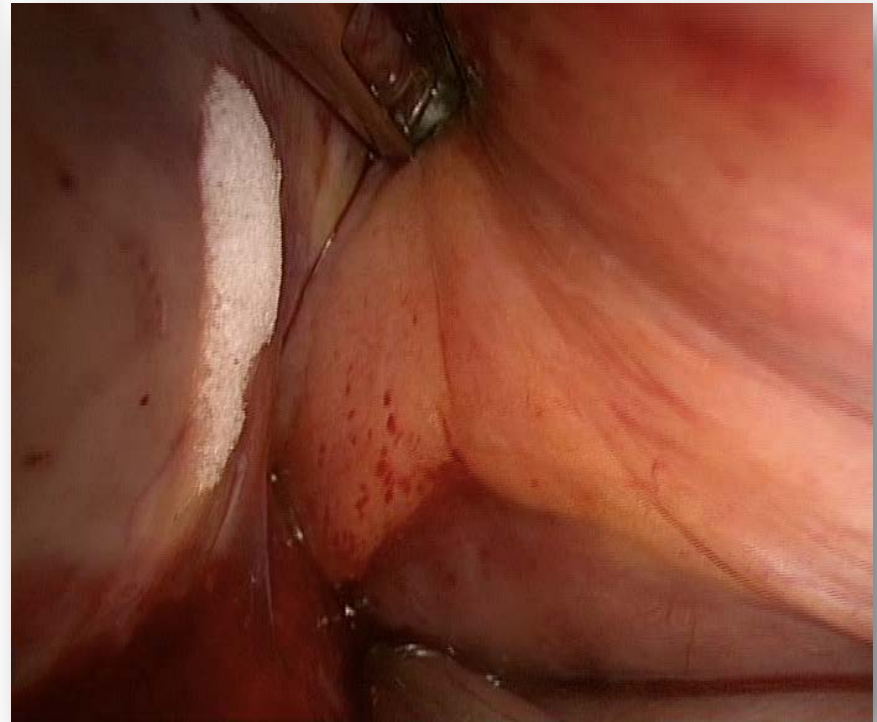


1st Generation Cryoballoon

Pison , Heart Rhythm 2010

2nd Generation Cryoballoon

de Asmundis , Chierchia GB, JCE 2013



1 year follow-up

Second-generation cryoballoon ablation for paroxysmal atrial fibrillation: 1-year follow-up

Gian-Battista Chierchia^{*†}, Giacomo Di Giovanni[†], Giuseppe Ciconte, Carlo de Asmundis, Giulio Conte, Juan Sieira-Moret, Moises Rodriguez-Mañero, Ruben Casado, Giannis Baltogiannis, Mehdi Namdar, Yukio Saitoh, Gaetano Paparella, Giacomo Mugnai, and Pedro Brugada

Heart Rhythm Management Center, UZ Brussel-VUB, Laarbeeklaan 101, 1090 Brussels, Belgium

Received 25 October 2013; accepted after revision 3 December 2013

- 42 patients; PAF
- Mean procedural time 95.2±16.2 ; mean fluoroscopic time 20.5±12.2 min
- After a single procedure 83% of patients were free of AF (BP 3 months)

One-Year Clinical Outcome After Pulmonary Vein Isolation Using the Second-Generation 28-mm Cryoballoon

Andreas Metzner, MD^{*}, Bruno Reissmann, MD^{*}, Peter Rausch, MD, Shibu Mathew, MD, Peter Wohlmuth, PhD, Roland Tilz, MD, Andreas Rillig, MD, Christine Lemes, MD, Sebastian Deiss, MD, Christian Heeger, MD, Masashi Kamioka, MD, Tina Lin, MD, Feifan Ouyang, MD, Karl-Heinz Kuck, MD and Erik Wissner, MD

 Author Affiliations

Correspondence to Andreas Metzner, MD, Asklepios-Klinik St Georg, Department of Cardiology, Lohmühlenstr 5, 20099 Hamburg, Germany. E-mail

- 50 patients; Short standing persistent AF 28% ; PAF 72%
- After a single procedure 80% of patients were free of AF

One-Year Follow-Up After Single Procedure Cryoballoon Ablation: A Comparison Between the First and Second Generation Balloon

GIACOMO DI GIOVANNI, M.D., KRISTEL WAUTERS, M.D., GIAN-BATTISTA CHIERCHIA, M.D., PH.D., JUAN SIEIRA, M.D., MOISES LEVINSTEIN, M.D., GIULIO CONTE, M.D., CARLO DE ASMUNDIS, M.D., PH.D., GIANNIS BALTOGIANNIS, M.D., PH.D., YUKIO SAITOH, M.D., GIUSEPPE CICONTE, M.D., JUSTO JULIA, M.D., GIACOMO MUGNAI, M.D., GHAZALA IRFAN, M.D., and PEDRO BRUGADA, M.D., PH.D.

From the Heart Rhythm Management Center, Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel, Brussels, Belgium

- 100 patients; 50 CB1; 50 CB2
- One year follow-up
- After a single procedure 66% vs 84% ($p=0,038$) of patients were free of AF

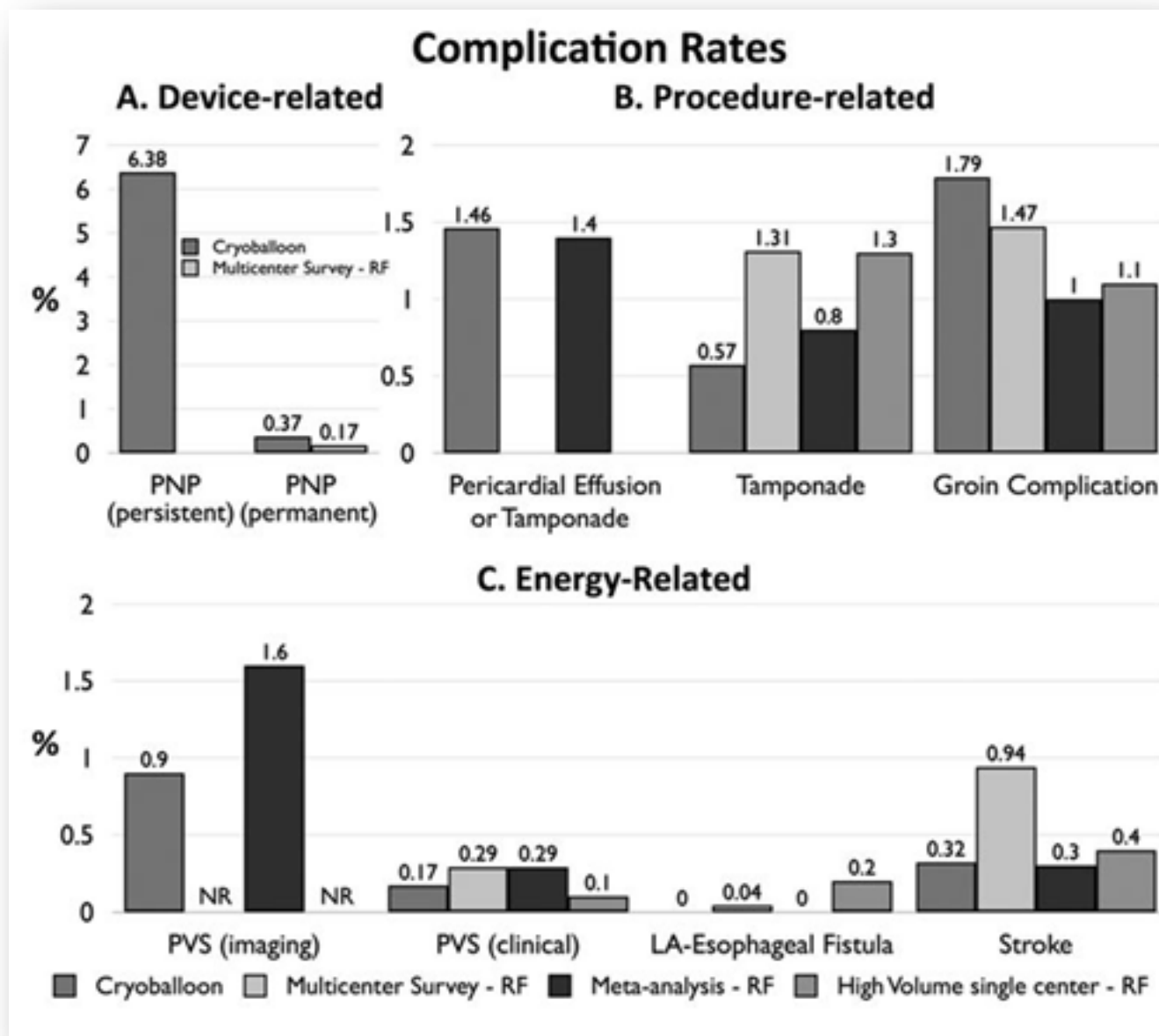
Improved 1-Year Clinical Success Rate of Pulmonary Vein Isolation with the Second-Generation Cryoballoon in Patients with Paroxysmal Atrial Fibrillation

ALEXANDER FÜRNKRANZ, M.D., STEFANO BORDIGNON, M.D., DANIELA DUGO, M.D., LAURA PEROTTA, M.D., MELANIE GUNAWARDENE, M.D., BRITTA SCHULTE-HAHN, M.D., BERND NOWAK, M.D., BORIS SCHMIDT, M.D., and JULIAN K.R. CHUN, M.D.

From the Cardioangiologisches Centrum Bethanien, Medizinische Klinik III, Markus Krankenhaus, Frankfurt, Germany

- 105 patients; 50 CB1; 55 CB2
- One year follow-up
- After a single procedure 63,9% vs 84% ($p=0,008$) of patients were free of AF

Complications



Andrade, Heart Rhythm 2011

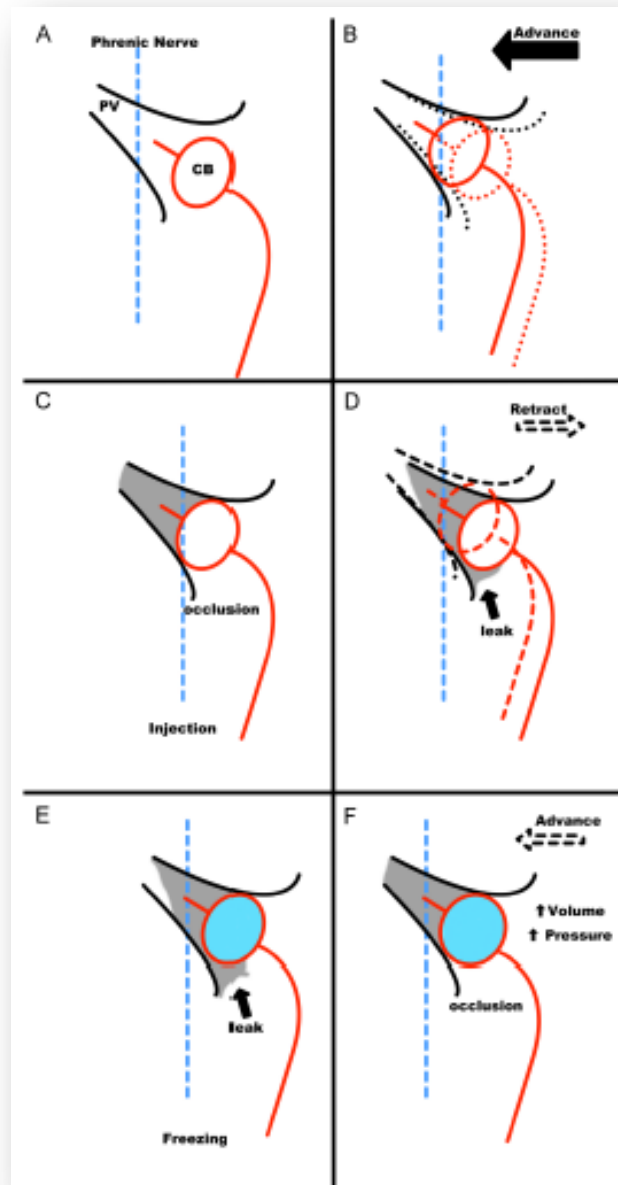
Phrenic nerve paralysis during cryoballoon ablation for atrial fibrillation: A comparison between the first- and second-generation balloon

Ruben Casado-Arroyo, MD, Gian-Battista Chierchia, MD, Giulio Conte, MD, Moisés Levinstein, MD, Juan Sieira, MD, Moises Rodriguez-Mañero, MD, Giacomo di Giovanni, MD, Yannis Baltogiannis, MD, Kristel Wauters, MD, Carlo de Asmundis, MD, PhD, Andrea Sarkozy, MD, PhD, Pedro Brugada, MD, PhD

From the Heart Rhythm Management Centre, Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel, Brussels, Belgium.

- All procedures with 28 mm
- PNP occurred in Group 1= 6,25% vs Group 2= 19%
- Approx 90% occurred in the first 8 patients
- No differences in T°C when PNP occurred

The proximal seal technique

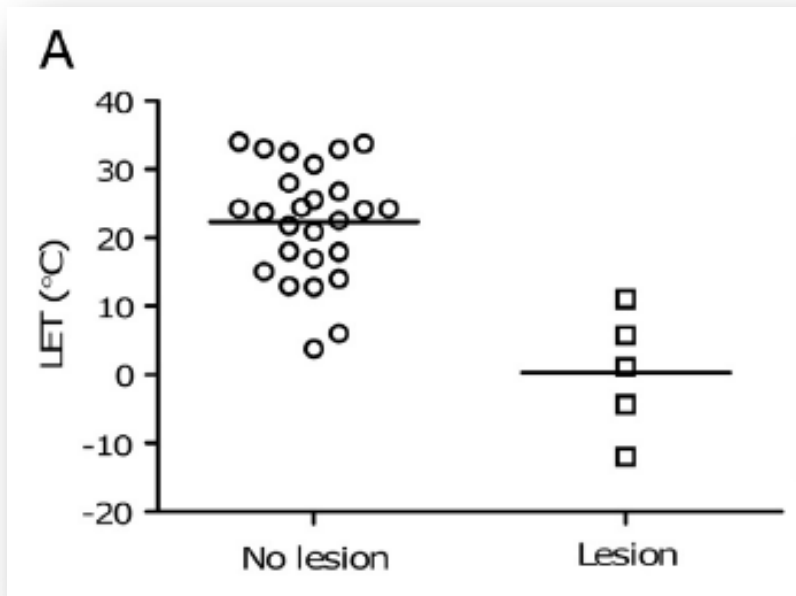


Luminal esophageal temperature predicts esophageal lesions after second-generation cryoballoon pulmonary vein isolation

Alexander Fürnkranz, MD,^{*} Stefano Bordignon, MD,^{*} Boris Schmidt, MD, FHRs,^{*} Michael Böhmig, MD,[†] Marie-Christine Böhmer, MD,[†] Frank Bode, MD,[‡] Britta Schulte-Hahn, MD,^{*} Bernd Nowak, MD,^{*} Axel U. Dignaß, MD,[†] Julian K.R. Chun, MD^{*}

From the ^{*}Cardioangiologisches Centrum Bethanien, Medizinische Klinik III, Markus Krankenhaus, Frankfurt, Germany, [†]Medizinische Klinik I, Markus Krankenhaus, Frankfurt, Germany, and [‡]Universitätsklinikum Medizinische Klinik II, Lübeck, Germany.





	Minimum LET (°C)	LET range (°C)	Minimum balloon temperature (°C)
LSPV	28.6 ± 7.5	5.8 to 36.0	-51 ± 6
LIPV	28.5 ± 9.3	-12.0 to 35.5	-47 ± 5
LCPV	31.1 ± 6.8	20.9 to 34.6	-54 ± 6
RSPV	33.8 ± 1.2	29.1 to 35.3	-50 ± 7
RIPV	28.2 ± 9.6	-4.3 to 34.9	-49 ± 6

- 19% of patients experienced esophageal lesions
- No lesion occurred with $LET > 12^{\circ}\text{C}$

Increased Incidence of Esophageal Thermal Lesions Using the Second-Generation 28-mm Cryoballoon

Andreas Metzner, MD; Andre Burchard, MD; Peter Wohlmuth; Peter Rausch, MD;
Alexander Bardyszewski, MD; Christina Gienapp; Roland Richard Tilz, MD; Andreas Rillig, MD;
Shibu Mathew, MD; Sebastian Deiss, MD; Hisaki Makimoto, MD; Feifan Ouyang, MD;
Karl-Heinz Kuck, MD, PhD; Erik Wissner, MD

What about shortening the freeze-thaw cycle duration?

Two Versus One Repeat Freeze–Thaw Cycle(s) After Cryoballoon Pulmonary Vein Isolation: The ALSTER EXTRA Pilot Study

KYOUNG RYUL JULIAN CHUN, M.D.,* ALEXANDER FÜRNKRANZ, M.D.,* ILKA KÖSTER, M.D., ANDREAS METZNER, M.D., TOBIAS TÖNNIS, M.D., PETER WOHLMUTH, ERIK WISSNER, M.D., BORIS SCHMIDT, M.D., FEIFAN OUYANG, M.D., and KARL HEINZ KUCK, M.D.

From the Department of Cardiology, Asklepios Klinik St. Georg, Hamburg, Germany

Conclusion

Application of 2 freeze–thaw cycles when compared to 1 freeze–thaw cycle following cryoballoon PVI did not result in improved clinical success but was associated with a higher complication rate.

“ The minimum recommended duration of 4 minutes was derived from studies on focal cryoablation realized more than 15 years ago and has not been rechallenged despite major innovations in catheter design and cryorefrigerants”

Initial experience of three-minute freeze cycles using the second-generation cryoballoon ablation: acute and short-term procedural outcomes

Gian-Battista Chierchia • Giacomo Di Giovanni • Juan Sieira-Moret • Carlo de Asmundis • Giulio Conte • Moises Rodriguez-Mañero • Ruben Casado-Arroyo • Giannis Baltogiannis • Gaetano Paparella • Giuseppe Ciconte • Andrea Sarkozy • Pedro Brugada

Received: 28 July 2013 / Accepted: 18 October 2013
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Table 3 Pulmonary vein isolation characteristics

LSPV	Time to isolation, s	47 (30)
	Temperature at isolation, °C	−37 (11)
LIPV	Time to isolation, s	30 (9)
	Temperature at isolation, °C	−26 (10)
RSPV	Time to isolation, s	29 (17)
	Temperature at isolation, °C	−28 (11)
RIPV	Time to isolation, s	51 (46)
	Temperature at isolation, °C	−32 (11)

LSPV left superior pulmonary vein, *LIPV* left inferior, *RSPV* right superior, *RIPV* right inferior

- Systematic bonus freeze after isolation in the first 24 pts
- No bonus freeze in the last 28 pts
- Mean number of freezes= 1,5 per vein
- At a mean follow-up of $5,7 \pm 2$ months, 82% of patients did not experience AF (no BP considered)
- No differences between both groups (bonus or not)

Summary

- Improved acute procedural outcome
- Reproducible single procedural 1 year success around 80-84%
- Different possible strategies: RT recordings, standard reduction of freeze cycle
- Bonus freeze