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CRYOABLATION WITH NEW GENERATION BALLOONS

Prof. Dr. med. Ellen Hoffmann
Heart Center Munich-Bogenhausen
Munich Municipal Hospital Group
Klinikum Bogenhausen
Munich, Germany

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Honoraria for lectures: Astra Zeneca, Boehringer Ingelheim, Boston Scientific, MSD Sharp & Dohme GMBH, Medtronic
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Venice, 16. Oct. 2015

CRYOABLATION
WITH NEW GENERATION BALLOONS

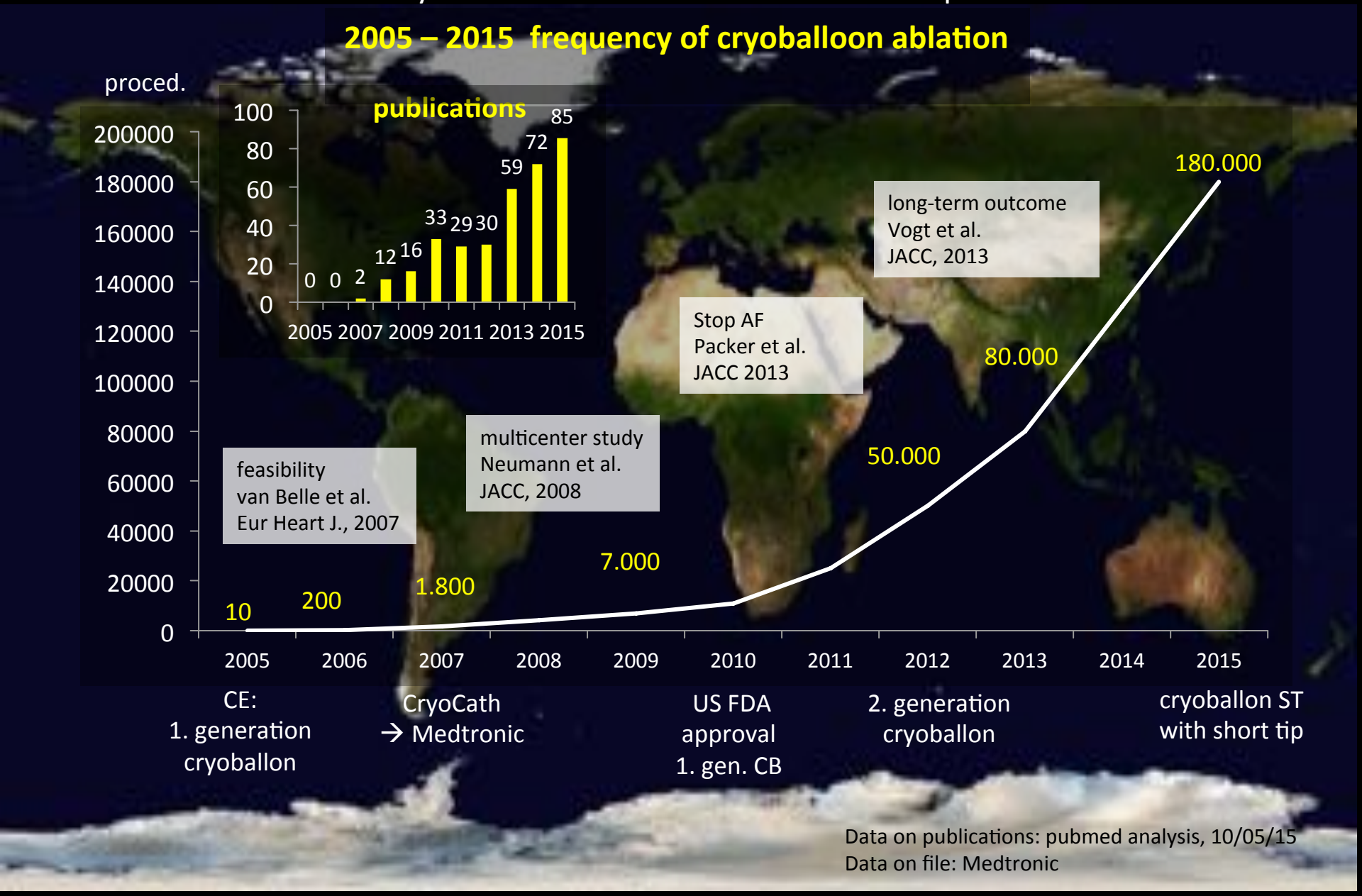
cryoballon ablation: 2005 - 2015

technological and procedural aspects

safety/efficacy in parox. and persist. AF

CRYOBALLOON ABLATION: 2005 - 2015

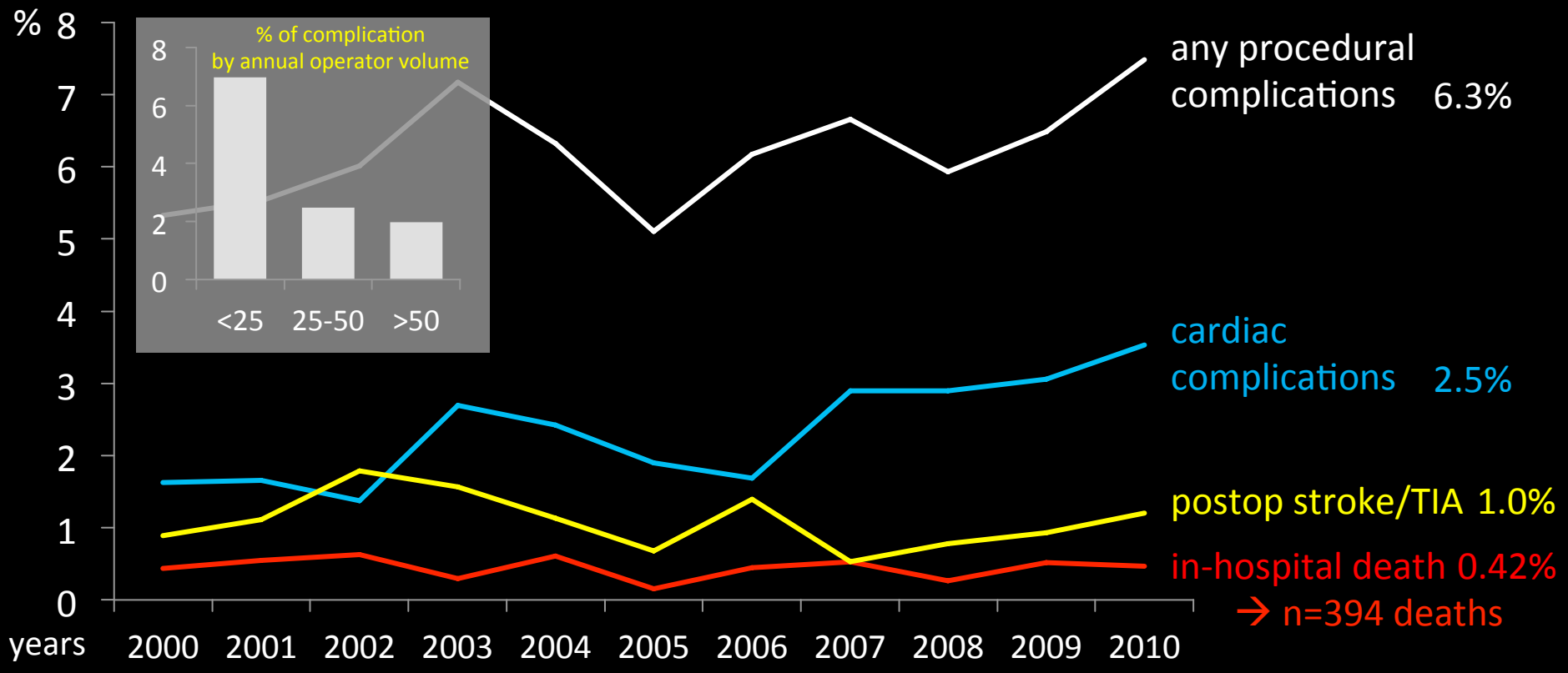
2015: >1000 active cryo consoles worldwide >500 in Europa and USA



Data on publications: pubmed analysis, 10/05/15
Data on file: Medtronic

TRENDS IN COMPLICATIONS FOR AF ABLATIONS

US Nationwide Inpatient Sample: In-Hospital Complications Associated With CA of AF between 2000 and 2010 n= 93,801 procedures



- overall complication rate: 6.3% in-hospital deaths: 394/93,801 (0.42%) in 10 yrs
- significant association between operator/hospital volume and adverse outcomes

→ need to identify the safety measures in AF ablations to improve overall outcome

Deshmukh et al., Circ 11/2013

CRYO: MAJOR COMPLICATIONS

	Andrade Heart Rhythm 2011 meta analysis n=1,349	Vogt JACC 2012 single-center n=605	Aryana JCE epub ahead 2015 multi-center n=773	Hoffmann own data status 8/2015 single-center n=1472
Death	0	0	n/a	0
AE fistula	0.00	0	n/a	0
Tamponade	0.57	0.2	n/a	0.2
Stroke or TIA	0.32	0.3	n/a	0.2
Pers.PNP <12 mon.	4.7	2.0	1.2	0.8
PNP >12 mon.	0.37	0	n/a	0.07
Other major AEs	2	2.2	1.6	0.8
Total	**3.2%**	**4.7%**	**2.8%**	**2.0%**

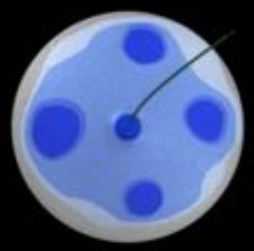
FDA data 4/15: 7 atrio-esophageal fistulas with 2nd CB / 100,000 ablation → 1:14.000

low major complication rate in cryoballoon ablation

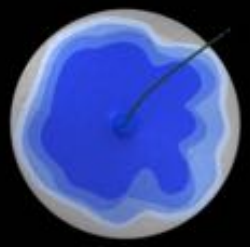
ADVANCES IN CRYOBALLOON-TECHNOLOGY

Surface temperature gradient

1st Gen.: Arctic Front™
Refrigerant spray pattern with 4 jets close to the equator



2nd Gen.: Arctic Front Adv.™
More uniform spray pattern with 8 more distal jets
Increased flow +16% (28 mm)

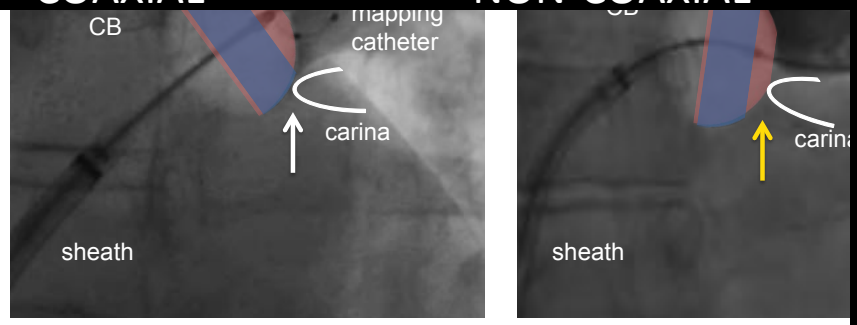


launched 5/2012

by courtesy of Medtronic, Inc.

Cooling zone and positioning

COAXIAL NON-COAXIAL



cooling zone
1st generation
2nd generation

Straube , Hoffmann et al. for the FREEZE Cohort Invest., Europace 2014

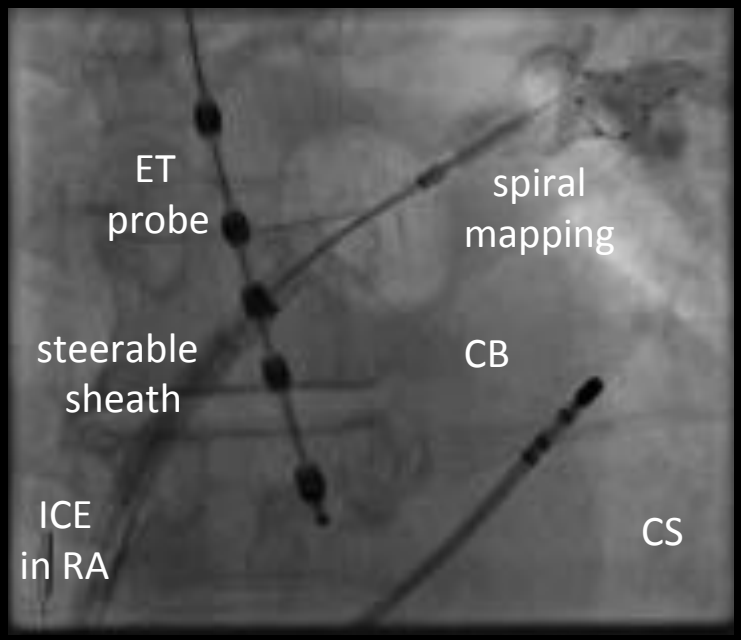
more uniform, extended freezing zone at the distal balloon hemisphere
need for coaxial alignment↓
→ contact of the optimal freezing zone even in difficult anatomies

CRYOBALLOON ABLATION FOR PVI

WITH REAL-TIME PV-POTENTIAL RECORDING AS A PREDICTOR OF EFFICACY

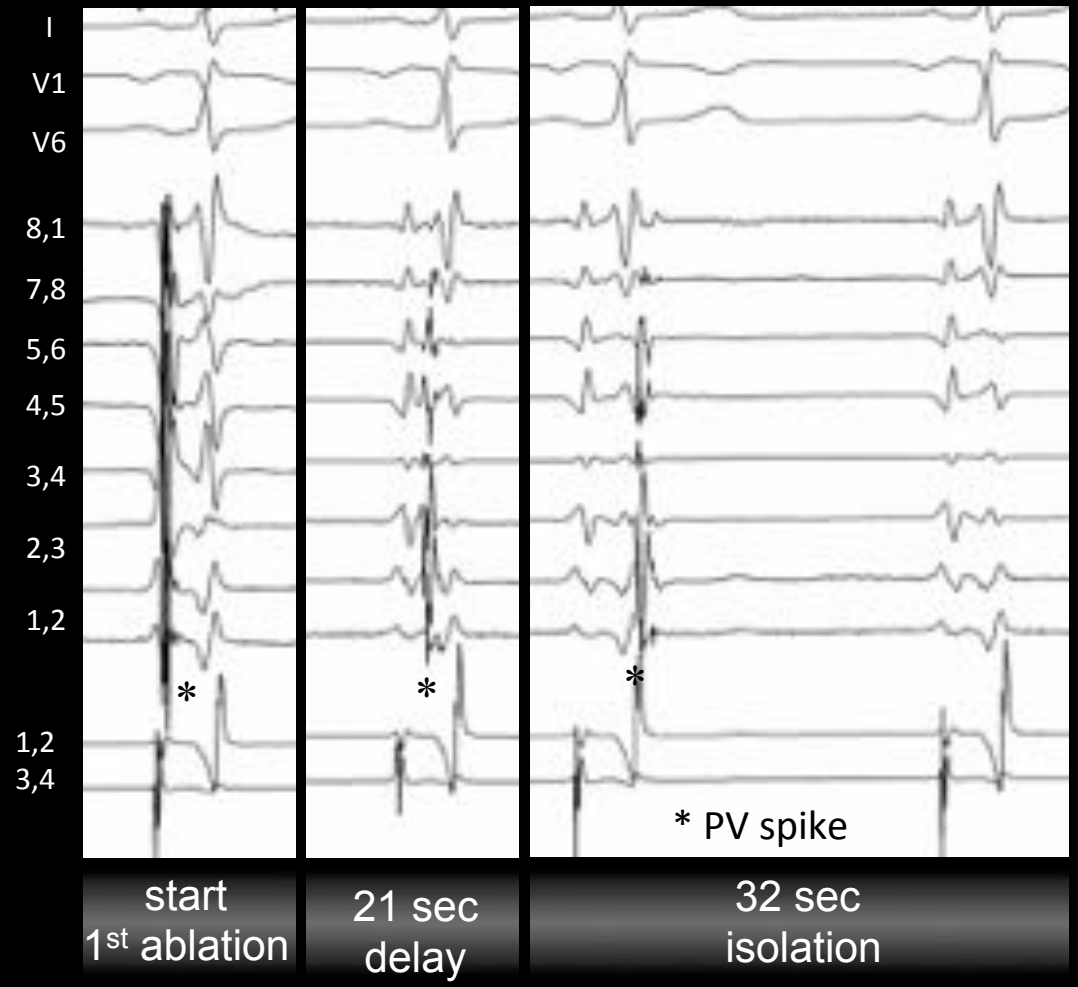
Isolation of LS-PV

CB 28 mm, spiral mapping catheter
Ø 1.1mm, 8 electrodes, 20mm loop



over the wire balloon technique

DETERMINATION OF "TIME TO PV ISOLATION (TTI)"



2nd gen. CB → single-shot in 70% of veins, TTI↓ → predictive for durable PVI

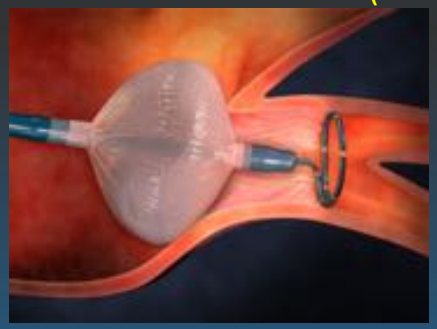
Straube, Hoffmann et al., Circ AEP, 2014

2nd GENERATION CRYOBALLON WITH SHORTENED TIP

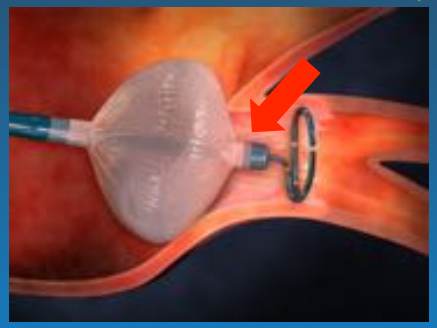
PRELIMINARY PROCEDURAL RESULTS

AFA-ST: distal tip -40% in length, no change in flowrate
→ aim: to obtain online PV potentials during ablation more frequently

Arctic Front Advance ™ (AFA)

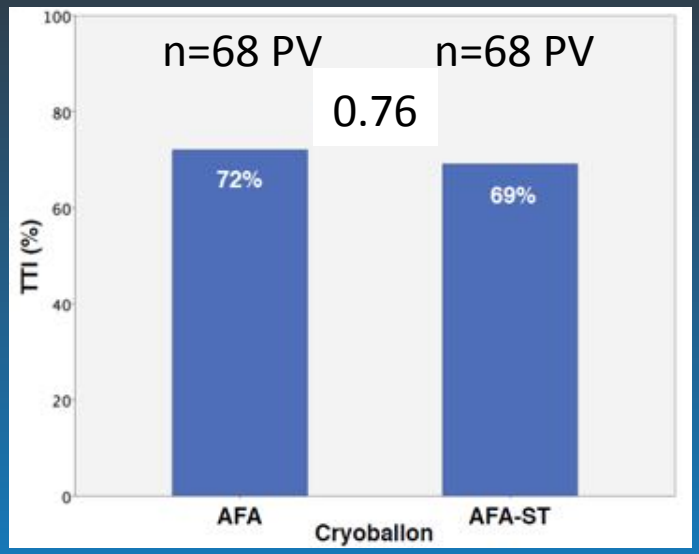


Arctic Front Advance ST ™ (AFA-ST)



n = 34 pts. / 136 PV

feasibility to determine the TTI

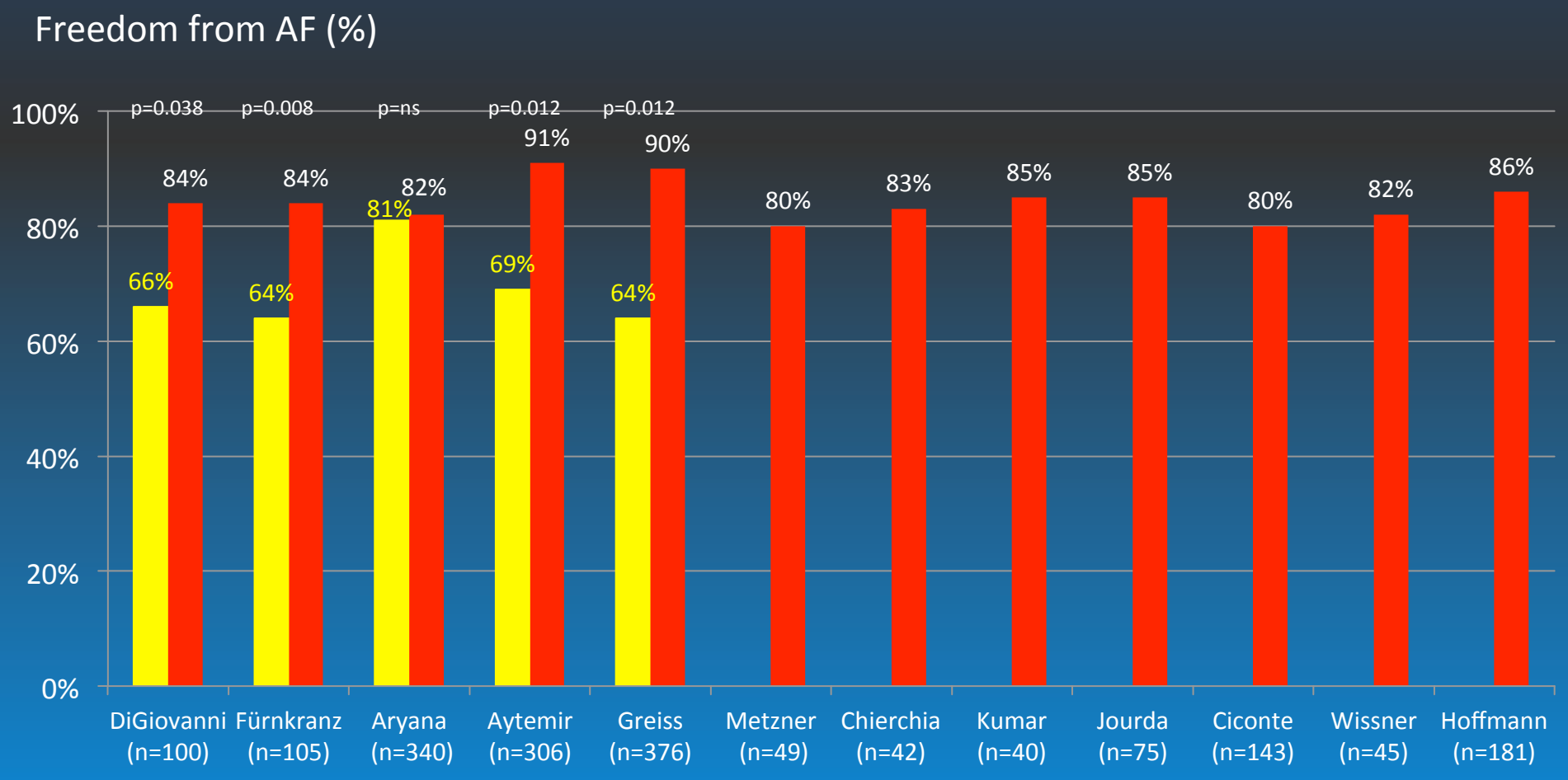


short tip of the cryoballoon → positioning of the spiral mapping more ostial
high rate of online PV potential recordings, until now no statistical difference

Bunz, Hoffmann et al, DGK Berlin, abstract, 10/09/15

OUTCOME OF CRYOABLATION STUDIES IN PAROXYSMAL AF AT 1 YEAR

cryoballon 1st generation 2nd generation



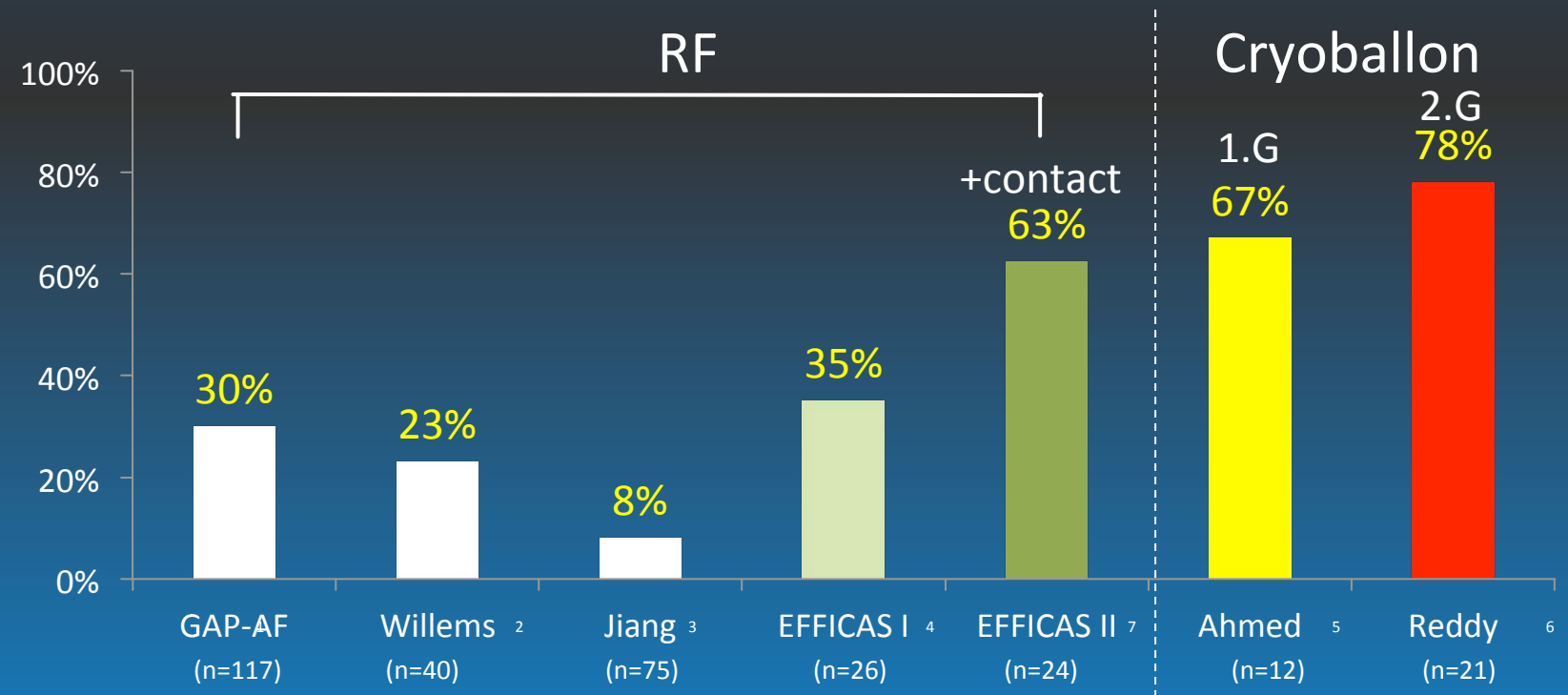
2nd generation cryoballon → success rate ~15%↑

reproducible and consistent results among different centers >80%

PATIENTS WITH ALL VEINS ISOLATED AFTER THE INTITIAL RF OR CB ABLATION AT SCHEDULED REMAP

consecutive invasive left atrial remap 3 mon. after PVI irrespectively of symptoms

% pts with all PVs isolated after the 1st procedure

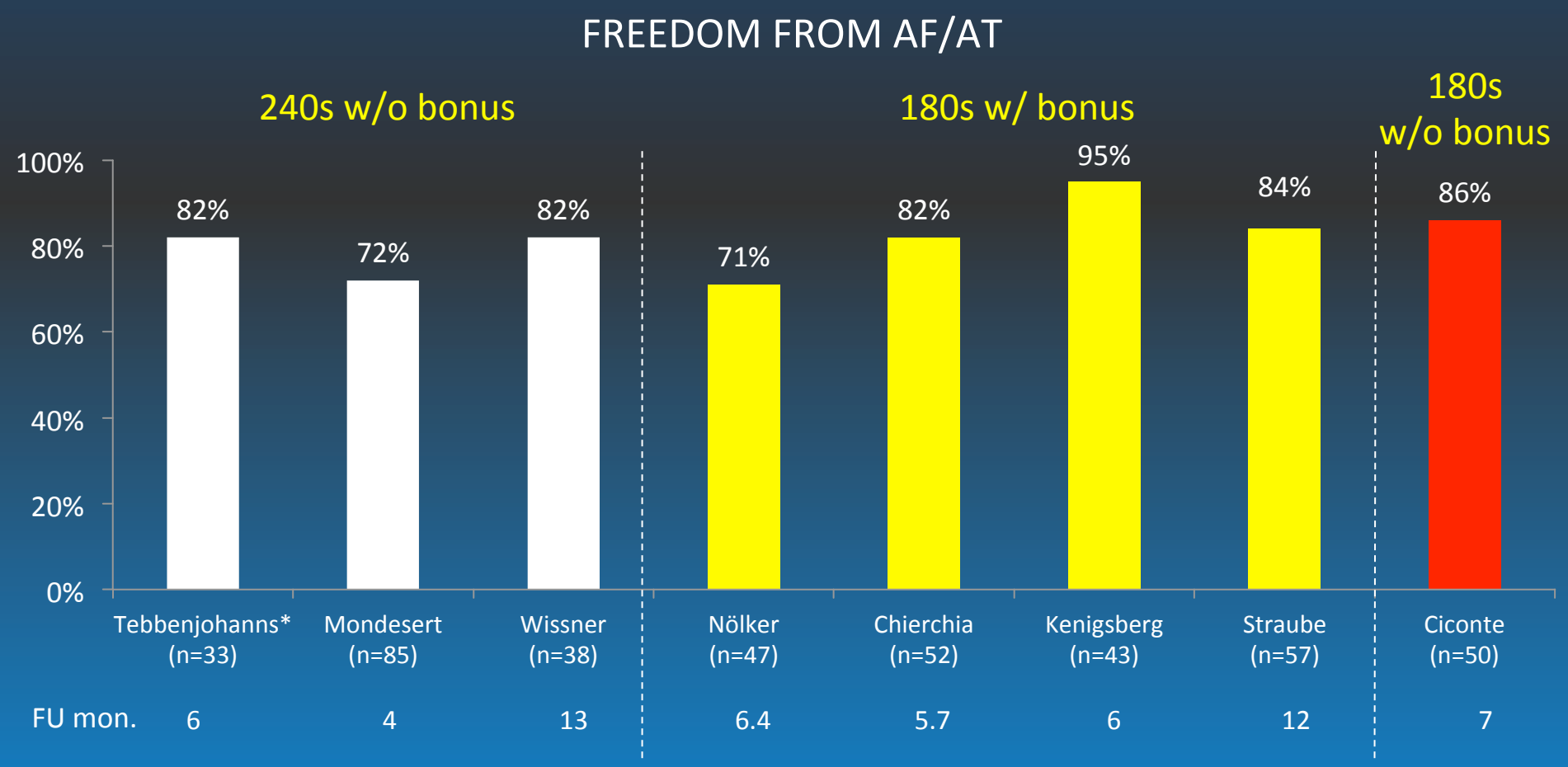


FU mon. bis remap	3	3	12	3	3	3	3,4

cryoballoon: high rate of durable isolated veins after the initial ablation
contact force sensing RFA → efficacy↑

[1]Late Breaking Clinical Trials session I at the EHRA EUROPACE 2013 meeting in Athens, Greece [2] Williems, et al. J Cardiovasc Electrophysiol 2010; 21(10):1079-84. [3] Jiang, et al. Heart Rhythm. 2014 [4] Neuzil et al. Circ Arrhythm Electrophysiol. 2013 [5,] Ahmed, et al. J Cardiovasc Electrophysiol, 2010; Reddy et al., JCE 2015, [7] Kautzner et al., Europace 2015

EVALUATION OF DIFFERENT CRYO-DOSING PROTOCOLS
WITH AND WITHOUT A BONUS APPLICATION AFTER ACUTE PVI



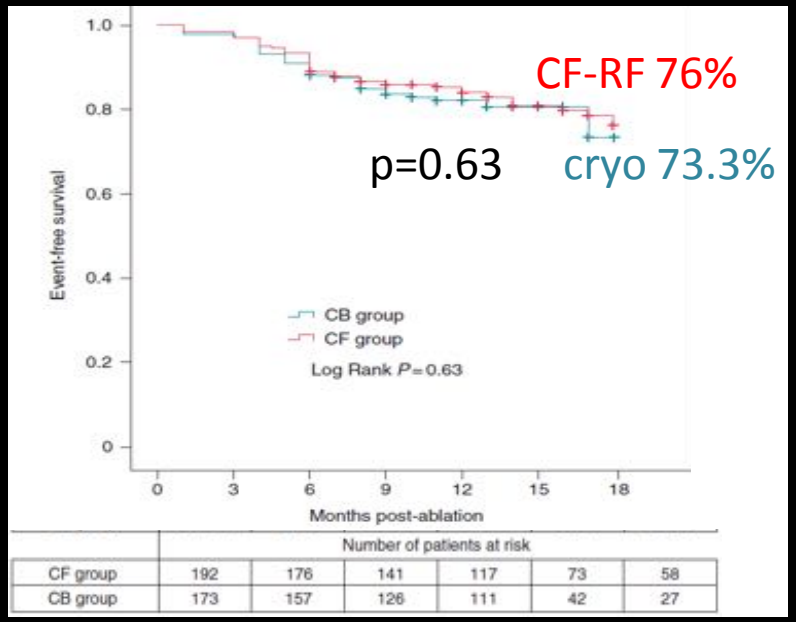
cryo ablation time↓ +/- bonus appl. → no effect on freedom from AF
however: short follow-up, no information on reconduction, small sample size

CONTACT FORCE RF VS. CB PVI: EFFICACY AND SAFETY

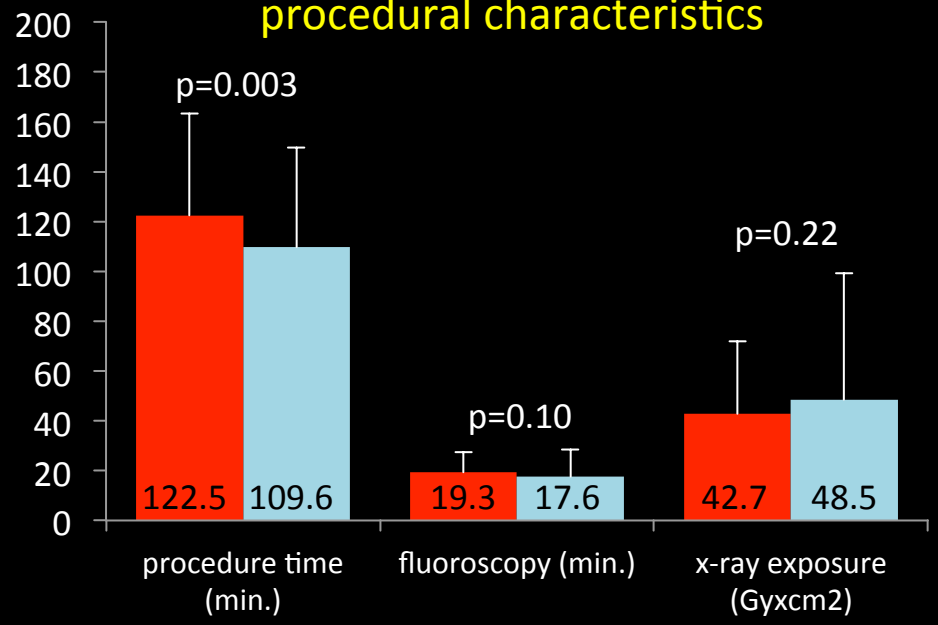
prosp. multicentre (4) observ. study n=376 PAF pts., 59.8 yrs 26% female

contact force RF n=198 cryoballoon n=178

freedom from atrial arrhythmias



procedural characteristics



complications	CF-RF			cryoablation	p value
total	7.1%			7.3% incl. 5.6% trans.PNP	0.93
severe	2 embolic ev. 1%	2 tamp. 1%	1 esoph.les. 0.5%	none	0.03

CF-RF and 2nd gen. cryoablation → comparable efficacy

severe complications more frequently observed with CF RF

Squara et al, Europace 2015

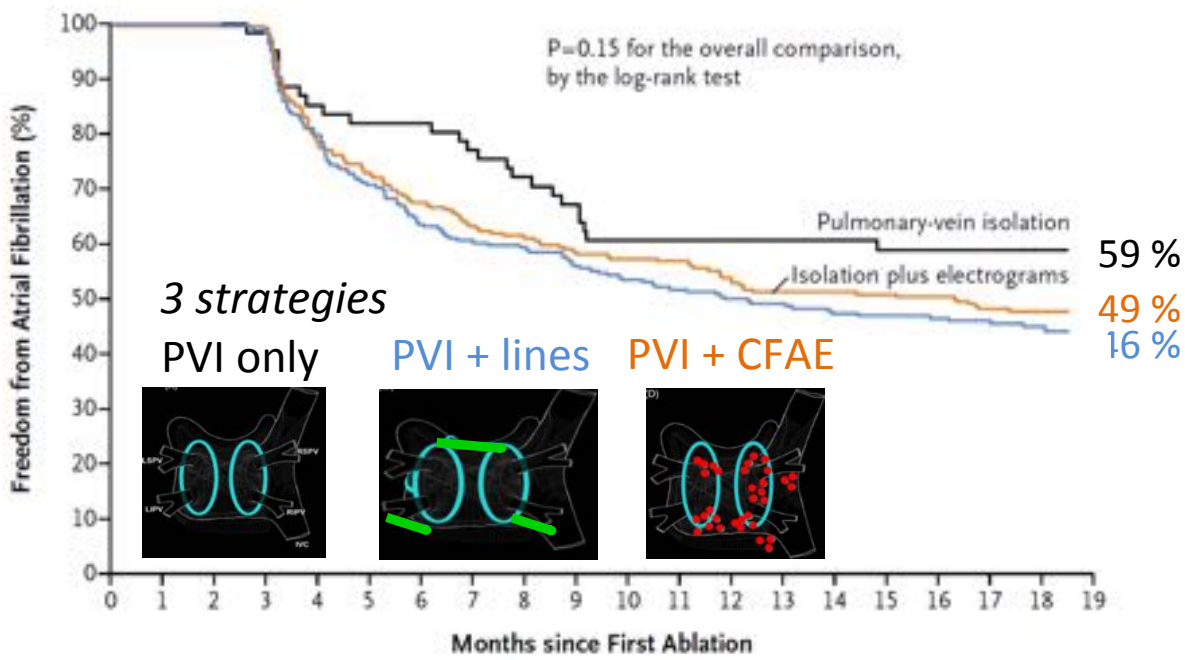
RF STRATEGIES FOR PERSISTENT AF

Substrate and **T**rigger **A**blation for **R**eduction of AF

first procedure, drug refractory pers. AF: n=589 pts., 48 centers, 12 countries

FREEDOM FROM AF >30s – SINGLE PROCEDURE SUCCESS

randomized
1:4:4



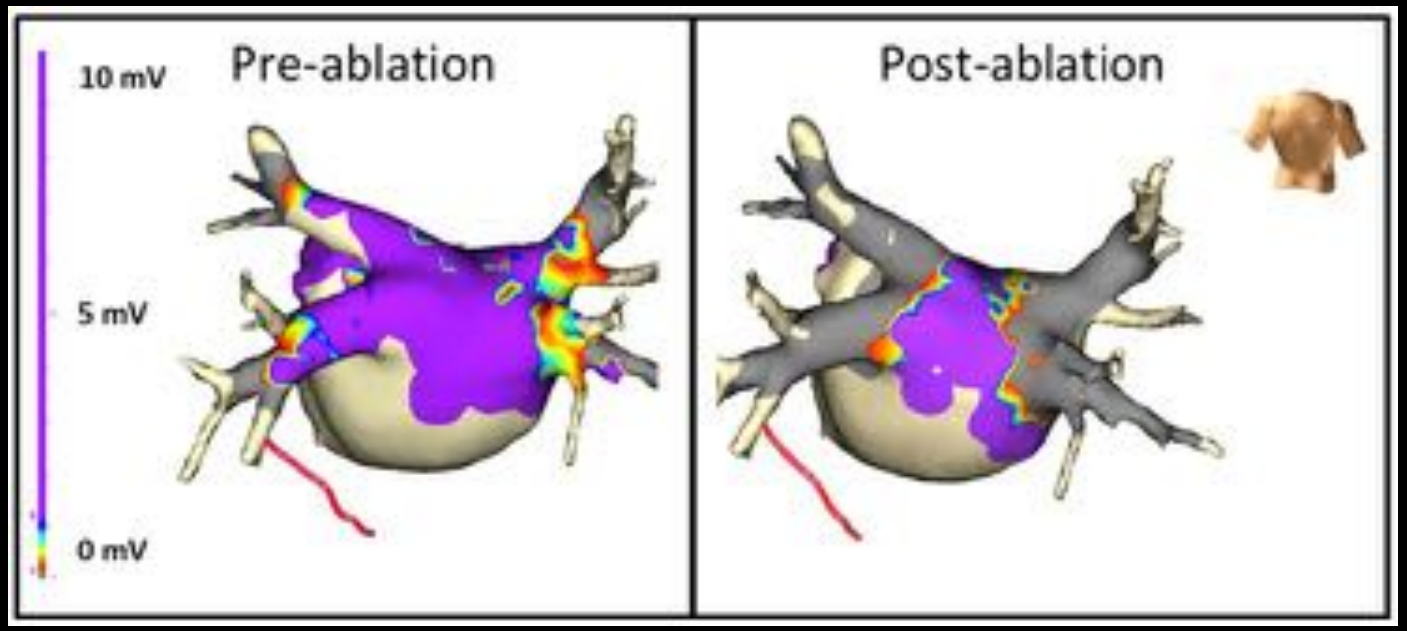
No. at Risk						
Pulmonary-vein isolation	61	60	50	41	36	23
Isolation plus electrograms	244	242	161	137	124	72
Isolation plus lines	244	240	152	133	115	57

Verma et al. , NEJM May 7 2015

persistent AF: „PVI only“ is a reasonable strategy for the index procedure

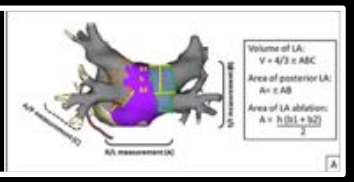
ABLATION LESION ZONE WITH 2ND GEN. CRYOBALLOON

3D electroanatomic voltage map pre- and post- PVI, merge with CT scan
n=43 patients



95% freedom from AF
at 6 months

LA post. wall:
73% ablated

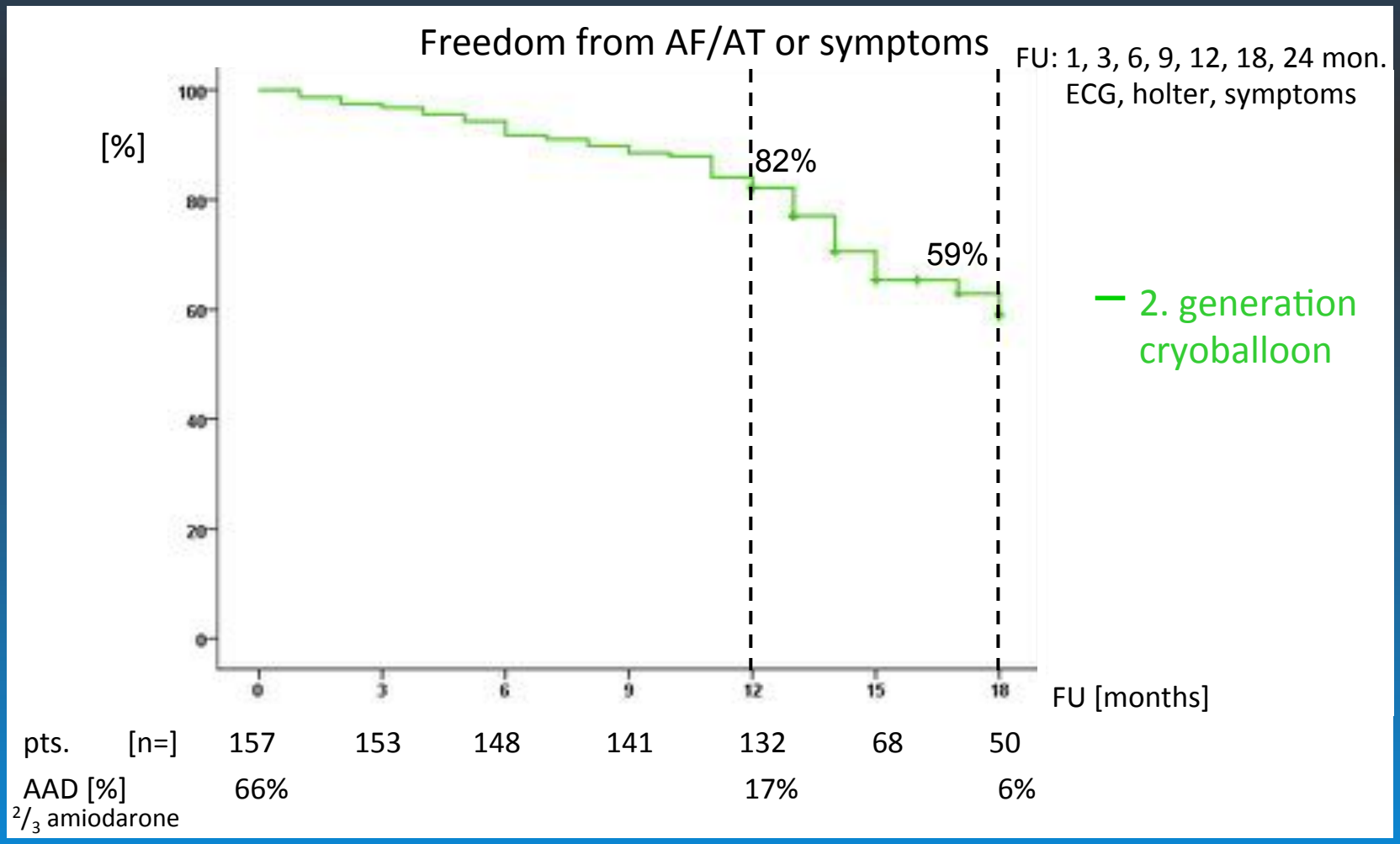


28mm cryoballoon: wide antral ablation lesion at the LA posterior wall
→ partly explains the efficacy beyond PV isolation

Kenigsberg, Heart Rhythm 2015

CRYOABLATION IN PERSISTENT AF: SINGLE PROCEDURE SUCCESS

n = 173 consec. pts. w/ refract. pers. AF, 64 yrs, LA 46±7 mm, EF 54%, HHD 24%, struct. HD 27%
AF duration 29 mon. (IQR 12-67) no. cardioversions 2.4±1.6



Cryoballoon ablation for persist. AF = safe and effective strategy for the intial procedure

Straube, Hartl, Dorwarth, Hoffmann et al., submitted for publication

CRYO- AND RADIOFREQUENCY ABLATION OF AF

ONGOING STUDIES COMPARING CRYO AND RF

FIRE AND ICE STUDY

PI: Karl-Heinz Kuck

Prospective randomized and multi-national comparison (PAF)

randomization

RF (n= 384)

Cryo (n= 384)

efficacy and safety at 1 year

status 8/2015

n = 768 (100%)
inclusion completed
FU ongoing

FREEZE COHORT STUDY

PI: Ellen Hoffmann

Prospective cohort comparative effectiveness trial (parox., persist.)

RF (n= 2000)

Cryo (n= 2000)

efficacy and safety at 1 year

funded by Medtronic

MULTINATIONAL FREEZE COHORT STUDY
CRYO- VS. RF-ABLATION

status: 06/10/2015

1. AF Ablation, parox. AF or persist. AF with prior AAD

Prospective comparative effectiveness cohort trial (parox., persist.), ITT

RF (n= 2000)

Cryo (n= 2000)

prim. endpoint: freedom from AF/AT at 1 year
efficacy, proc. parameters, complications

experienced centers ≥ 50 RF or ≥ 50 Cryo prior to participation
40 active centers: 18 RF, 22 Cryo

Cohort ITT

Cryo:	**2049**
RF:	**1806**
Total:	**3855**

4,000 patients at the end of 2015

Freeze Plus Registry

Cryo	579
RF	973
total	1552

Austria, China, Germany, Greece, Netherlands, Poland, South Africa, Spain, US

Principle Investigor: Ellen Hoffmann

supported by Medtronic

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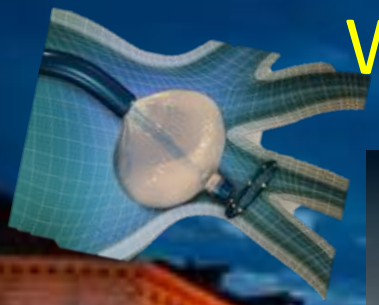

open questions

procedural param.: bonus freeze?, 3-4 min appl. time?
preferential technique for the index proc.: Cryo vs. RF?
→ results from the FIRE&ICE and FREEZE Cohort Study

persistent atrial fibrillation

cryoballoon: reasonable option for the index procedure
→ high rate of durable PVI
→ wide antral ablation lesion, fast procedure

safety and efficacy

10 years of cryoballoon ablation: evidence↑, acceptance↑
complications↓, reproducible and consistent results